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Between Scylla and Charybdis: Patentability and Morality Related to Human Embryonic Stem Cells

Li Jiang

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Between Scylla and Charybdis: Patentability and Morality Related to Human Embryonic Stem Cells

BETWEEN SCYLLA AND CHARYBDIS: PATENTABILITY AND MORALITY RELATED TO HUMAN EMBRYONIC STEM CELLS

LI JIANG*

ABSTRACT

The patentability of inventions related to Human Embryonic Stem Cells (HESC) is challenged by the morality provision of various nations' regulations.¹ This Article discusses whether it is a matter of expediency to prohibit granting patents to HESC-related inventions based on morality-based provisions, and it concludes that this is not appropriate. To claim this, the Article explores typical cases and regulations in the European Union, United States, and China. However, different areas adopt various approaches in dealing with this extremely complex issue. This comparison sheds light on the inappropriate combination of morality and patentability in the EU and China. The comparison of these areas also demonstrates infusing patent law with morality is both inefficient and ineffective as morality is not a criterion that patent authorities should consider.

* Li Jiang holds a Ph.D. from Bangor University Law School, a LL. M from Shandong University, and a B.S. in Biotechnology from University of Science and Technology Beijing. The author would like to thank Dr Shi Wei for his invaluable input, as well as the staff of the Intellectual Property Brief for their tremendous work and care, without which this publication would not be possible.

1. See Article 53(a) of European Patent Convention (stating that "European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States"); see also Article 5 of Patent Law of the People's Republic of China (stating that patent rights shall not be granted for invention-creations that violate the law or social ethics or harm public interests); Article 32 of Korean Patent Law (stating that inventions liable to contravene the public order or morality or cause injury to the public health shall not be patentable).

Additionally, in terms of funds invested into research, the reward of a patent seems to have been overvalued. This Article argues that it is better to establish the specific authority to monitor HESC research instead of infusing morality with patentability. A patent system without a moral clause would be beneficial to move HESC research forward.

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INTRODUCTION

Inventions related to Human Embryonic Stem Cells (HESC) as a patentable subject matter are in considerable flux.² In most circumstances,

2. See Amanda Odell West, *The Absence of Informed Consent to Commercial Exploitation for Inventions Developed from Human Biological Material: A Bar to Patentability?*, 3 INTELL. PROP. Q. 373, 390 (2009) (arguing that inventions using human biological matter should submit “evidence of ethical approval” with its application to the EPO); Amanda Warren-Jones, *A Mouse in Sheep’s Clothing: The Challenge to the Patent Morality Criterion Posed by “Dolly”*, 20 EUR. INTELL. PROP. REV. 445, 450 (1998) (discussing the obstacles presented to HESC-related inventions under the current European patent system); see also Graeme Laurie, *Patenting Stem Cells of Human Origin*, 26 EUR. INTELL. PROP. REV. 59, 59 (2004) (expressing concern over the “bioethical aspects of the

morality and law may not coincide, yet moral obstacles are significant for inventions related to HESC research. Patent examiners inevitably encounter moral issues when examining applications related to HESC. The connection between law and morality in HESC is natural and “hardly new.”³ The creation, operation, and interpretation of the patent system is inherently linked to moral standards.⁴ Some consider the marriage of law and morality in this area to be in “a hopelessly confused state.”⁵

Different from the patentability of other inventions, morality plays an important role in patenting HESC inventions. Therefore, we must ask whether it is reasonable to reject HESC inventions on moral grounds. Every jurisdiction develops its own answer to this question due to the diversity of moral standards and the territorial patent system.⁶ On the one hand, the patent prohibition of HESC related inventions based on morality issues is unreasonable since the supposedly immoral research has already been carried out.⁷ This immoral research should neither be funded nor initiated instead of being ineligible for patenting because, even if prohibited from patenting, the immoral research has already been carried out. Moral considerations are deeply rooted in the EU—and this is even true in the United Kingdom, which has liberal policies towards HESC research.⁸ In the EU, in order to harmonize HESC regulation, regulators have erected a

law”).

3. See Peter Drahos, *Biotechnology Patents, Markets and Morality*, 21 EUR. INTELL. PROP. REV. 441, 441 (1999) (pointing out “[s]ome areas of law invite adjudicators to draw on morality in the process of legal decision-making. Somewhat surprisingly, given its characterization as a tool of economic regulation, patent law does just this . . . The express connection between patent law and morality is hardly new”).

4. *Id.*

5. See Laurie, *supra* note 2 at 65 (stating that the introduction of HESC technology has demonstrated that the system is flawed).

6. For example, the US patent system does not preclude patenting HESC inventions. See U.S. Patent, No. 5,843,780 (filed Jan. 18, 1996) (issued Dec. 1, 1998), U.S. Patent No. 6,200,806 (filed Jun. 26, 1998) (issued Mar. 13, 2001), and U.S. Patent No. 7,029,913 (filed Oct. 18, 2001) (issued Apr. 18, 2006). The EU patent system precludes patenting HESC inventions; see generally *Use of embryos/WARF*, G 2/06 [2009] 5 OJ EPO 306.

7. See generally *Use of embryos/WARF*, G 2/06 [2009] 5 OJ EPO 306 (explaining that practicing the invention conflicts with concepts of morality, not the act of patenting the invention).

8. See Aurora Plomer, *Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the UK*, 10 MED. L. REV. 132, 132-44 (2002) (stating that “[t]he UK currently stands alone in Europe in permitting the creation of human embryos specifically for research purposes, including the use of cloning techniques”); see also Dame Mary Warnock DBE, *The Warnock Report*, HUMAN FERTILIZATION AND EMBRYOLOGY AUTHORITIES (June 26, 1984), available at <http://www.hfea.gov.uk/2068.html> (discussing two extreme views: one is from members of the Catholic Church who believe human embryos have human status, and another is from utilitarians who insist human embryos have no moral status).

moral barrier to patenting HESC-related inventions.⁹ The moral barrier in patent law is ineffective and inefficient. First, although the European Patent Convention made a great effort to harmonize the patentability and morality of HESC through the EU Biotechnology Directive,¹⁰ the morality standards for patentability are inconsistently interpreted, specifically by including the definitions for morality, human embryo, industrial use, and commercial use.¹¹ In addition, the European Court of Justice (ECJ) and the European Patent Office's (EPO) dual system of assessing morality standards has resulted in legal uncertainty.¹² Also, member states have different interpretations for adapting the moral exclusion of the European Patent Convention.¹³ This legal inconsistency has added procedural complexity and thus hampered technological advancement. Second, many HESC related research projects are funded by the EU; however, the results of these research projects cannot be patented.¹⁴ Taken to its logical end, 'immoral' research should not receive EU funding in the first place if it cannot later be patented for these reasons. If the research could be funded by the EU, this research should be morally examined before being concluded because funding research projects that are precluded from patent protection is a waste of money and time. Therefore, we should reconsider how much patent law can accommodate morality issues.

9. Article 53(a) of European Patent Convention ("European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to 'ordre public' or morality.").

10. See Article 53(a) of European Patent Convention; Directive 98/44/EC of the European Parliament and of the Council: Of July 6, 1998 of the Legal Protection of Biotechnological Inventions (arguing for greater legal protections for biotechnological inventions).

11. See Laurie, *supra* note 2 at 59-66 (stating that "despite the fact that disquiet and discussions of an ethic nature held up the adoption of the biotechnology Directive for so long, it is far from clear that we are any further forward in developing uniform, logical, principled, and defensible ethical guidelines within European patent law").

12. See generally *Use of embryos/WARF*, G 2/06 [2009] 5 *OJ EPO*.306.

13. See generally ÅSA HELLSTADIUS, A COMPARATIVE ANALYSIS OF THE NATIONAL IMPLEMENTATION OF THE DIRECTIVE'S MORALITY CLAUSE, IN EMBRYONIC STEM CELL PATENTS: EUROPEAN PATENT LAW AND ETHICS 96-148 (Aurora Plomer & Paul Torremans eds., 1st ed. Oxford University Press) (2009).

14. "Since 2007, the EU had funded twenty-seven collaborative health research projects involving the use of human embryonic stem cells with an EU contribution of about €157 million. Human embryonic stem cell research projects represent approximately one third of health projects on all forms of stem cells. In addition, the European Research Council had funded 10 projects for an EU financial contribution of about €19 million and there have been twenty-four Marie Skłodowska-Curie actions involving human embryonic stem cell research worth €23 million." *European Citizens' Initiative: European Commission replies to 'One of Us' – Q&A*, European Commission (May 28, 2014), europa.eu/rapid/press-release_MEMO-14-385_en.doc.

On the other hand, the patent prohibition of HESC-related inventions based on morality issues does not seem to be an effective method of controlling immoral research. For example, although China's patent law contains a moral exclusion clause, doctors remain uncertain as to the types of research they are permitted to conduct due to ambivalence towards moral and medical risks.¹⁵ This article takes the view that the adoption of the moral exclusion clause in patent law by Chinese regulators merely reflects the perception that the moral exclusion represents an international custom. However, interpretations of the moral exclusion clause in patent law are severely lacking. The considerable gap left by the moral provision makes it confusing and controversial. There are reports of many promising stem cell therapies, such as stem cell therapy for cardiac repair, Graft-Versus-Host disease, limb ischemia, liver disease, and neural repair being conducted in Chinese hospitals.¹⁶ However, these therapies are still not tested by clinic trial and are unsafe for patients. In response to pressure from stem cell market demands, some scientists from areas with restrictive policies, such as the EU, will move to areas that have permissive policies or alternatively, some might conduct research in more permissive regions, such as China. Thus, HESC research involving cloning and other sensitive procedures will become more difficult to monitor, resulting in biomedical adventurism, which may disrupt the legal and social infrastructure of the world.¹⁷

This article then discusses whether HESC research can be monitored in circumstances when morality issues are not the barriers to patenting. After exploring the U.S.'s HESC-related regulations, the author believes that it is technically manageable and pragmatically meaningful to supervise HESC research without moral exclusion in patent law. For example, there is no moral exclusion in US patent regulation.¹⁸ The U.S. government takes a rather practical approach of patenting in order to remain competitive in the HESC market.¹⁹ HESC-related inventions are not prohibited from

15. Ole Döring, *China's Struggle for Practical Regulations in Medical Ethics*, 4 NATURE REV. GENETICS 233-39 (2003).

16. See Lianming Liao and Robert Chunhua Zhao, *An Overview of Stem-Cell Based Clinical Trials in China*, 17 STEM CELLS AND DEV. 613, 613-618 (2008) (discussing China's progressive "therapeutic application" of stem cell technologies).

17. Ole Döring, *Chinese Researchers Promote Biomedical Regulations: What are the Motives of the Biopolitical Dawn in China and Where are they Heading?*, 14 KENNEDY INST. ETHICS J. 39, 42 (2004) (commenting that "the positivistic principle 'if an action is not illegal, by definition, it is legal' does not apply in China. Taking advantage of the fact that policymaking lags behind scientific and economic development, in terms of the entire legal and social infrastructure, amounts to biomedical adventurism").

18. 35 U.S.C. §§ 101-103.

19. See generally Comment, Gabriel S. Gross, *Federally Funding Human Embryonic*

patenting for moral reasons.²⁰ Federal funding is only used for morally acceptable HESC research, which provides an important tool for monitoring HESC research.²¹ Although this hands-off approach is market orientated,²² opponents have strongly criticized this approach for its lack of ethical and social considerations.²³ This article argues that funding control is a better way to monitor HESC research. From an economic perspective, deciding to prohibit immoral research at the initial stage saves both time and money.

The above comparison of the U.S., EU, and China demonstrates that integrating morality into patent law is both inefficient and ineffective. Morality is not a criterion that patent authorities should be tasked with assessing. Even if the results of HESC research cannot be patented, it could still be performed and funded. However, immoral research should be prohibited from the outset instead of at the patent application stage. Moreover, from an economic point of view, restricting immoral research from the beginning could save a tremendous amount of time and money. Additionally, in terms of funds invested into research, the reward of a patent seems to have been overvalued. A patent system without a moral clause would be more beneficial for advancing HESC research. The EU and Chinese Patent Offices should not be responsible for examining the morality of HESC inventions; instead, these decisions should be left to separate special organization, such as the Ethics Committee. Therefore, this Article argues that it would be more economically viable to implement specific legal regulations applicable to HESC research than to include a general moral exclusion in the patent law.

This Article presents moral concerns surrounding HESC patenting in three parts. Part I explores the incongruous interpretations of moral standards and “industrial or commercial use” in EU case law. The inconsistent interpretation of moral provisions has resulted in controversy and confusion in the patentability of HESC-related inventions, which would certainly become a barrier to technological progress. Part II

Stem Cell Research: An Administrative Analysis, 2000 WIS. L. REV. 855, 858, 883 (2000) (using the “Chevron Two-Step” to analyze the Department of Health and Human Services’ interpretation of federal law governing stem cell research funding).

20. §§ 101-103.

21. See Gross, *supra* note 19.

22. National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research, Volume 1 Report and Recommendations of the National Advisory Commission* (Sept. 13, 1999), available at <https://bioethicsarchive.georgetown.edu/nbac/stemcell.pdf>.

23. See Michael J. Malinowsk & Nick Littlefield, *Transformation of a Research Platform Into Commercial Products: The Impact of US Federal Policy on Biotechnology*, THE COMMERCIALIZATION OF GENETIC RESEARCH: ETHICAL, LEGAL, AND POLICY ISSUES 80, 80 (Timothy A. Caulfield & Bryn Williams-Jones eds., 1st ed. 1999).

examines the effect of moral provisions in the Chinese patent system. The vast interpretive scope left by China's moral provision makes this provision confusing and controversial. The uncertain interpretation regarding morality and patentability of HESC-related invention results in poor supervision of HESC research. Part III discusses the developing policies of HESC research in the U.S. Instead of moral exclusion in patentability, the U.S. regulates and controls federal funding. The federal funding control of HESC research may provide an alternative approach to patent control. Moreover, the inconsistent policies adopted by different administrations leave the patentability of HESC-related inventions vulnerable to market demands. Through a detailed, section-by-section comparison of each approach adopted in these three areas, this Article demonstrates that moral exclusion is unnecessary in patent law.

I. THE EUROPEAN UNION: INCONSISTENT INTERPRETATIONS OF MORAL PROVISIONS IN PATENT LAW

The EU regulation of HESC research related to moral concerns infuses patent examination with a moral assessment.²⁴ Despite many scholars' and legal practitioners' belief that patent law is not the proper vehicle for enforcing morality and that patent examiners are not moral experts,²⁵ the EU patent-granting agencies are responsible for interpreting moral provisions.²⁶ European Biotechnology Directive 98/44/EC explicitly states that inventions that involve the "use[] of human embryos for industrial or commercial purpose" cannot be patented.²⁷ However, the question

24. See Article 53(a) of European Patent Convention (stating "European patents shall not be granted in respect of (a) inventions the commercial exploitation of which would be contrary to 'ordre public' or morality").

25. See *Leland Stanford/MODIFIED ANIMALS*, 2002 EPOR 2, at point 51 (stating the Opposition Division of European Patent Office has noticed this difference and commented that "it cannot be the role of the EPO to act as a moral censor and invoke the provisions of Article 53(a) EPC to refuse on ethical grounds to grant a patent on legal research and directed to an invention indisputably associated with medical benefits"); see William Cornish, David Llewelyn, & Tanya Aplin, *INTELLECTUAL PROPERTY: PATENTS, COPYRIGHT, TRADEMARKS AND ALLIED RIGHTS* 881 (7th ed. 2010) (pointing out that morality and patent law should be divided because patent system is not an appropriated arena for moral discussion); see also Julia Black, *Regulation as Facilitation: Negotiating the Genetic Revolution*, 61 MOD. L. REV. 621, 649 (1998) (stating that the objective, technical and legal nature of patent law is contrary to the morality that is inherently "malleable, subjective and emotive").

26. See *Relaxin/Howard Florey Institute*, T 0272/95 [2002] EPOR; see also *Plant Genetic Systems/Glutamine Synthetase Inhibitors*, T356/93 [1995] EPOR 361; *HARVARD/Onco-mouse*, T19/90, [1990].

27. Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, art. 42, 1998 O.J. (L 213).

remains: how should the law assess morality along with the scope of the industrial or commercial use referenced in the Directive?

A. How to assess the morality?

At the EU level, the European Patent Convention contains a morality clause that excludes patenting immoral inventions,²⁸ whereas the morality standard developed in case law has established inconsistent standards (i.e., “abhorrence” versus “unacceptability”).

1. Howard Florey/Relaxin: the “abhorrence” standard with rebuttable presumption approach

The “abhorrence” standard is drawn from *Howard Florey/Relaxin*,²⁹ which considers a patent application related to the DNA sequence coding for relaxin—the unexpected second form of the human hormone that helps relax the uterus during childbirth and reduce the need for Cesarean sections.³⁰ The patent was initially granted in 1991, but the Green Party opposed it in the European Parliament. One of the Green Party’s primary objections was that the issuance of the patent was contrary to morality.³¹ The Opposition Division of the Patent Office first cited the “abhorrence” standard established in the *Plant Genetic Systems* case.³² The Opposition Division then established a “rebuttable presumption”³³ approach to the “abhorrence” standard.³⁴ Based on this standard, the *Relaxin* patent did not

28. Article 53(a) of European Patent Convention (stating that “[e]uropean patents shall not be granted in respect of . . . inventions the commercial exploitation of which would be contrary to ‘ordre public’ or morality”).

29. *Relaxin*, 1995 OJ EPO 388 (Opposition Div. 1994) (holding that the the test for the abhorrence standard is whether it is probable that the general public would find the invention so abhorrent that granting patent rights would be inconceivable.).

30. See F. GARY CUNNINGHAM ET AL., WILLIAMS OBSTETRICS 41 (Dwight Rouse et al, eds., 22d ed. 2005) (explaining the role of relaxin to “promote uterine vascular vasodilation and myometrial smooth muscle relaxation); see generally R. Stephen Crespi, *The Human Embryo and Patent Law—A Major Challenge Ahead?*, 28 EUR. INTELL. PROP. REV. 569 (2006) (discussing the effect of developing biotechnologies on the patent laws in industrialized countries).

31. *Case T-0272/95, Relaxin/Howard Florey Institute*, [2002] EPOR (summarizing that the Green Party opposed the European patent 112.149 that was granted to the Howard Florey Institute of Experimental Physiology and Medicine for human H-2 relaxin, a hormone involved in reproduction, and a DNA sequence coding for the hormone).

32. *Case T-356/93, Plant cells/Plant Genetic Systems*, [1995] EPOR (“It would undoubtedly be against ‘ordre public’ or morality to propose a misuse or destructive use of these [genetic engineering] techniques.”).

33. See Yan Min, *Morality —An Equivocal Area in the Patent System*, 34 EUR. INTELL. PROP. REV. 261, 263 (2012).

34. See *Relaxin*, 1995 OJ EPO 388 (holding that “[a] fair test to apply is to consider

go against “widely-accepted moral standards of behavior”, therefore, the Green Party’s morality objection is invalid.³⁵

This decision applies the general principle of narrowly interpreting the exclusion of patentability.³⁶ When the opponent requested to conduct a public survey of “what would be patentable,” the Opposition Division refused to issue it and indicated that the EPO is not the proper organization to determine fundamental moral questions.³⁷ Therefore, to some extent, the “abhorrence” standard is much lower than the “unacceptability” standard discussed below.

2. *Harvard/Onco-mouse: The “unacceptability” standard*

The “unacceptability” standard is mainly implied in the “*Onco-mouse*” case, which involves the patentability of genetically modified mice that are useful in cancer research.³⁸ In 1992, the Examining Division granted the Onco-mouse patent,³⁹ which was then challenged on the ground that the invention violated the morality requirement of Article 53(a) of the European Patent Convention (EPC).⁴⁰ The Technical Appeal Board (TBA) cited the “unacceptability” definition in *Plant Genetic Systems v. Greenpeace* as the possible reason for unpatentability.⁴¹ The TBA therefore developed the “unacceptability” standard, which balances the “acceptable suffering” and “unacceptable suffering.”⁴² The analysis from this balancing test in this case weighed in favor of patentability due to the invention’s massive benefits.

whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Article 53(a); otherwise not”).

35. See Yan Min, *supra* note 33 (internal quotation marks omitted).

36. For a rationale of the Directive, see Crespi, *supra* note 30, at 571.

37. See *R. v. Leland Stanford/MODIFIED ANIMALS*, [2002] EPOR 2 (Opposition Div. 2001). at point 51 (stating the Opposition Division of European Patent Office has commented that “it cannot be the role of the EPO to act as a moral censor and invoke the provisions of Article 53(a) EPC to refuse on ethical grounds to grant a patent on legal research and directed to an invention indisputably associated with medical benefits”).

38. *Case T-19/90, Onco-mouse/HARVARD* (EPO 1990).

39. *Eur. Patent No. 0 169 672 A1* (filed June 24, 1985) (detailing the method for producing transgenic animals).

40. See Article 53(a).

41. See *Case T-356/93, Plant cells/Plant Genetic Systems*, [1995] EPOR 16 (stating that “the concept of morality is related to the belief that some behavior is right and acceptable, whereas other behavior is wrong, and this belief is founded on the totality of the accepted norms that are deeply rooted in a particular culture”).

42. *Case T-315/03, Transgenic animal/Harvard*, [2005] EPOR 2, 8, 17 (explaining how the TBA weighs the suffering of animals and possible risks to the environment and the invention’s usefulness to mankind).

The EPO has therefore developed two moral standards: a balancing test to determine whether the “unacceptability” standard applies as well as a rebuttable presumption that the “abhorrence” standard applies. The “abhorrence” standard provides minimum morality-based protections.⁴³ The “unacceptability” standard is frequently implicated in patent applications related to life.⁴⁴ The EPO can adopt different moral standards during the initial examination and the appeal stages of a human biotechnology patent application.⁴⁵ The two above-mentioned methodologies are fundamentally different: “the ‘balancing exercise’ incorporate[s] diverse issues in direct competition to each other;” conversely, “the ‘rebuttable presumption’ [examines] a raft of issues to determine if any one of them [constitutes] an ‘abhorrence.’”⁴⁶ The distinction between these two standards is significant because “under the ‘balancing exercise’ all of the issues considered form part of the reason why the invention is patentable or not: whereas the ‘rebuttable presumption’ approach identifies a single issue upon which the decision rests.”⁴⁷ In the foreseeable future, the equivocal interpretations of the moral provision in patent law will be a barrier to the great medical potential.⁴⁸

3. *Plant Genetic Systems v. Greenpeace: The conflict between “abhorrence” standard and “unacceptability” standard*

Both the “abhorrence” and “unacceptability” standards are discussed and

43. See Margo A. Bagley, *A Global Controversy: The Role of Morality in Biotechnology Patent Law*, 57 U. VA. L. SCH. PUB. L. & LEGAL THEORY WORKING PAPER SERIES 332, 333, 335 (2007) (commenting that this “unacceptability” standard is certainly a lower hurdle for an invention to overcome than the balancing test); see also Min, *supra* note 33 at 264.

44. See Min, *supra* note 33 at 264 (explaining how this standard most likely applies to animal and plant biotechnology).

45. Amanda Warren-Jones, *Finding a “Common Morality Codex” For Biotech—A Question of Substance*, 39 INT’L REV. INTELL. PROP. & COMPETITION L. 638, 652-53 (2008).

46. *Id.* at 653.

47. *Id.* (observing that the difference between the two standards can be the difference between the patentee being able to resolve the problem by amending the claim or having to consign the invention to ignominy).

48. See Min, *supra* note 33 at 265 (commenting that “[t]his is because, on one hand, the so-called morality exception is favoured by the Greens, animal welfare activists and environmentalists as a powerful weapon against biotechnology inventions, and consequently they prefer a stricter moral standard which is in stark contrast to the proponents of genetic engineering who prefer a loose standard; and on the other hand, in contemporary society there are few, if any, inventions so obviously immoral as to raise little difficulty in denying a grant of patent on the ground of morality”).

applied in *Plant Genetic Systems*. This case involved the application for a patent in glutamine synthetase inhibitors that help plants and seeds resist weeds and fungal diseases.⁴⁹ The granted patent was challenged by Greenpeace, which argued that it created serious environmental risks.⁵⁰

The Opposition Division initially refused to exercise the balancing test established in the *Onco-mouse* case by claiming that the “unacceptability” standard is not the only way to assess patentability.⁵¹ Because the moral provision acts as an emergency safeguard, the Opposition Division further stated that patents should not be granted for inventions that are universally regarded as outrageous.⁵² The reason that the Opposition Division adopted the “abhorrence” standard instead of the “unacceptability” balancing test was that “balancing does not even come into play unless concrete societal disadvantages of the invention are presented.”⁵³ Therefore, the Opposition Division held that only “in those very limited cases in which there is an overwhelming consensus that the exploitation of an invention would be immoral may an invention be excluded from patentability under Article 53(a).”⁵⁴

By contrast, the TBA seems to apply the “unacceptability” rather than the “abhorrence” standard. Based on the interpretation of morality by the TBA,⁵⁵ an assessment of morality cannot possibly be achieved by balancing benefits and disadvantages because there is no sufficient evidence of true benefits or disadvantages.⁵⁶ However, the possibility

49. *Case T-356/93, Plant cells/Plant Genetic Systems*, [1995] EPOR 24.

50. *Id.* at 8 (explaining that “[t]he exploitation of the present invention resulted in serious, irreversible environmental risks: the treated plants themselves could become weeds; Herbicide-resistance could spread to other plants; [and] the ecosystems could be damaged”).

51. *Id.* at 12 (disclosing that the Opposition Division found that the “invention did not belong to the category of inventions which the public in general would have regarded as being so abhorrent or so dangerous that the grant of patent rights should have been inconceivable. The EPO should apply the exclusions from patentability under Article 53(a) EPC only in such extreme cases”).

52. *See id.*; see also Amanda Warren-Jones, *Vital Parameters for Patent Morality—A Question of Form*, 2 J. INTELL. PROP. L. & PRAC. 832, 837 n.31 (2007).

53. *See Bagley*, *supra* note 43 at 333.

54. *See Warren-Jones*, *supra* note 45 at 642.

55. *See Case T-356/93, Plant cells/Plant Genetic Systems*, [1995] EPOR (TBA) at 16 (explaining that due to the nature of the EPC, the TBA historically explained “the concept of morality is related to the belief that some behavior is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms that are deeply rooted in a particular culture”).

56. *Id.* at 18 (“In the present case, since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability with regard to Article 53(a) EPC may not be based on the so-called ‘balancing exercise’ of benefits and disadvantages, as submitted by the Appellants. The Board observes that such a ‘balancing exercise’ is not the only way

remains that a morality assessment could involve assessing potential benefits and disadvantages. Different from the *Onco-mouse* case where the environmental risk is an appropriate consideration for unacceptable patent, in *Plant Genetic Systems*, the Board found “the possibility of risks traditionally has no bearing on whether a patent is granted or not.”⁵⁷

The above analysis shows that the EPO conducts moral assessments inconsistently, leading to a cycle of misapplication. Even in the EPO’s decisions, two competing standards, “abhorrence” and “unacceptability,” may be applied. Moreover, this dual system provides no clear guidance on which approach is appropriate in any particular case.⁵⁸ This confusion is well demonstrated in *Plant Genetic Systems* because it would apply the “rebuttable presumption” approach to the “abhorrence” standard. The only remaining issue would be “how this standard and methodology are to operate in practice [which would] require[] an analysis of the evidence [that] forms the basis of the decision.”⁵⁹ Amanda Warren-Jones, a legal scholar from University of Sheffield, advances three arguments to favor the abhorrence approach.⁶⁰ While alternatively, it may be improper to balance issues involving human-beings from either an ethical or an evidentiary perspective.⁶¹

B. Whether HESC-related inventions should be included in “human embryo?” What is the scope of “industrial or commercial use?”

Another enduring ambiguous aspect of morality is commercial exploitation. The scope of the “industrial or commercial use” in Article 53(a) of the EPC determines the arena for the moral assessment. In patent examination, morality is capable of being determined only if commercial

of assessing patentability with regard to Article 53(a) EPC, but just one possible way, perhaps useful in situations in which an actual damage and/or disadvantage (e.g. suffering of animals as in the case of decision T 19/90) exists.”).

57. *Id.* at 31.

58. Warren-Jones, *supra* note 45, at 654 (analyzing this issue and arguing that “only one defensible approach . . . offers cohesion in the European patent system”).

59. *Id.*

60. *Id.* at 653 (arguing that first, unlike the “unacceptability” standard that covers all issues related to whether a patent should be granted, the “abhorrence” standard focuses on a single issue on which to base a decision. Second, “it is not possible to weigh competing issues to determine ‘abhorrence’ because [that concept] is an absolute that does not permit fine [logical distinctions] in the way that ‘unacceptability’ does.” Third, the EPO has already identified cases involving “abhorrent” inventions. Only when such examinations are appealed based on that issue might a decision be reversed).

61. *Id.* at 654-61 (noting that “[t]he President in the WARF case pointed out that adoption of a ‘balancing exercise’ at the initial examination stage imposes an ethical assessment beyond the ability and mandate of patent offices”).

exploitation has been assured.⁶²

1. University of Edinburgh: A broad approach by the Opposition Division on the interpretation of “human embryos”

The scope of the exclusion of the “use of human embryos for industrial or commercial use” was first addressed in *University of Edinburgh/Stem Cell Isolation*.⁶³ That case involved a European patent held by the University of Edinburgh’s Austin Smith and Peter Mountford and addressed methods of selecting for animal stem cells (including HESC).⁶⁴ To further complicate matters, a term used in the patent claim referred to animals, but did not exclude humans.⁶⁵ Accordingly, fourteen parties opposed the patent, including those of Germany and the Netherlands, because it might cover HESC, not just animal stem cells. Those parties filed in the Opposition Division⁶⁶ on the ground that granting the patent would violate Article 53(a) of the EPC.⁶⁷

The Opposition Division distinguished between fact and opinion and finally concluded that, based on the Biotechnology Directive, HESC-related inventions derived from destruction of human embryos are not patentable.⁶⁸ First, the Opposition Division acknowledged two opposing views concerning the scope of the term “human embryo,” as used in Article 53(a) of the EPC: the narrow interpretation was understood to mean “human embryos” and the broad interpretation was understood to mean “human embryos together with the cells retrieved from the destruction of those embryos—namely, human ES cells.”⁶⁹ Next, the Opposition Division noted that Article 53(a) of the EPC is equivalent to Article 6(2) of the

62. Warren-Jones, *supra* note 2, at 447 (observing that “[e]xamination at the patenting stage requires that morality be determined before exploitation has become assured[, and that] it is [therefore] inevitable that any assessment at such an early stage in the invention’s commercial development will entail some considerations which will consequentially prove superfluous”).

63. *Case T-1079/03, University of Edinburgh/Stem Cell Isolation (Edinburgh)*, EP 949131742 unreported, July 21, 2003, Opposition Division.

64. *Id.*

65. *Id.*

66. *Id.*

67. *Directive 98/44/EC, of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, art. [1998] 42 *OJ EPO* (L 213) (stating within the preamble of the Council Directive that European patents should not be granted for inventions involving “uses of human embryos for industrial or commercial purposes”).

68. *University of Edinburgh/Stem Cell Isolation (Edinburgh)*, T-1079/03 EP 949131742 unreported, July 21, 2003, Opposition Division.

69. Crespi, *supra* note 30, at 572.

Directive.⁷⁰ The interpretation of the Directive towards the morality of HESC-related inventions, as set forth in its recitals, is that HESC fall within the scope of the term “human embryo.”⁷¹ Thus, the Opposition Division held that the broad interpretation was appropriate.

With regard to the term “industrial or commercial use,” the Opposition Division stressed that “use” of HESC-related invention should be considered patenting in the event that such invention is morally acceptable.⁷² In *University of Edinburgh/Stem Cell Isolation*, the application refers to using HESC which were obtained by destroying human embryos; since using HESCs was ethically unacceptable, it is unnecessary to consider patenting the “use” of such invention. Under the Opposition Division’s ruling, it is also immoral to use spare embryos from in vitro fertilization (“IVF”) procedures and embryos created for research since both involve the destruction of human embryos.⁷³

However, a former board of Appeal Member at the EPO, Claudio Germinario, expressed a different opinion; specifically, that to conform to a previous TBA ruling, the term “human embryo” in Article 6(2) of the Directive should be interpreted narrowly.⁷⁴ He pointed out that “the scope

70. *Council Directive 98/44/EC*, art. 6, 1998 O.J. (L 213) (EC). The directive provides: “Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ‘ordre public’ or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation On the basis of paragraph one, the following, in particular, shall be considered unpatentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; and (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.” *Compare id.* with Article 53(a) European Patent Convention; *see University of Edinburgh/Stem Cell Isolation* (Edinburgh), T-1079/03 EP 949131742 unreported, July 21, 2003, Opposition Division, at 22.

71. Recital 16 of the Directive provides that “it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented.” *Council Directive 98/44/EC*, ¶ 16, 1998 O.J. (L 213) (EC).

72. *University of Edinburgh/Stem Cell Isolation* (Edinburgh), T-1079/03 EP 949131742 unreported, July 21, 2003, Opposition Division (stating that if the patenting of a product is ethically unacceptable, it is hardly conceivable that the patenting of “uses” of this product could be judged differently).

73. *Id.*

74. Claudio Germinario, *The Value of Life*, 163 PATENT WORLD 16, 18 (2004) (arguing that the function of the patent claims in defining the scope of protection provides a practical workable solution to these issues. Thus insofar as the actual claims themselves do not encompass any reference to the embryo or preceding step in which the embryo is actually used).

of the protection conferred by a patent is given by the wording of the claims interpreted.”⁷⁵ He believed that since the destruction process was not claimed, patenting HESCs was not a violation even though these cells were derived from human embryo.⁷⁶ He further stated that if HESCs are “available through importation or from many other sources,” the patent application does not necessarily include “the prohibited stage of producing the first generation of freshly disaggregated embryonic cells.”⁷⁷ Therefore, no moral prohibition should be used against using the imported human ES cells.⁷⁸

2. Use of embryos/WARF (G2/06): The landmark ruling by the European Patent Office (EPO) patenting HESC

WARF addressed the same questions as *University of Edinburgh*.⁷⁹ This case involved a European patent application by the Wisconsin Alumni Research Foundation (WARF) titled “Primate embryonic stem cells,” covering the derivation and cultures of pluripotent embryonic stem cell lines.⁸⁰ The patent description shows that WARF’s claims address inventions obtained through a method that involves destroying human embryos.⁸¹ Although the application does not directly claim that method, human embryos are inevitably destroyed because the method is the only way to obtain the invention.⁸² In 2004, the EPO’s Examining Division denied the application.⁸³ The examiners held that the claims violated Article 53(a), in conjunction with Rule 28(c) of EPC 2000,⁸⁴ because “as

75. *Id.*

76. *Id.* (stating that although admittedly any such process must begin with the destruction of a human embryo this would appear to be immaterial to the patenting of the process and cell lines thus obtained in so far as the prohibited step is not claimed.).

77. *Id.*

78. *Id.* (applying his analysis to the University of Edinburgh case).

79. *See generally Use of embryos/WARF*, G 2/06 [2009] 5 *OJ EPO* 306.

80. Eur. Pat. App. No. 96,903,521 published as EP0770125 (claiming that a cell culture comprising primate embryonic stem cells that “(i) are capable of proliferation in an in vitro culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered by the culturing, (iii) maintain the potential throughout the culture to differentiate into derivatives of endoderm, mesoderm, and ectoderm tissues, and (iv) are prevented from differentiating when cultured on a fibroblast feeder layer.”).

81. *Use of embryos/WARF*, G 2/06, [2009] 5 *OJ EPO*, at 308 (EPO Enlarged Board of Appeal 2009).

82. *Id.*

83. *Id.* at 309.

84. *See id.*; *see also* Implementing Regulations, European Patent Convention, Nov. 29, 2000, Rule 28(c) (providing that “[u]nder Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the

regards the generation of human embryonic stem cell cultures, the use of human embryos as starting material was described in the application as originally filed as being indispensable.”⁸⁵ Although the patent application did not directly claim human embryos, the invention is related to them and exclusively relies on them.⁸⁶ The examiners also concluded that the use of human embryos as a starting material is a use for industrial purposes within the scope of Rule 28(c) of the EPC 2000, and therefore could not be patented.⁸⁷

The decision was appealed and turned over to the Board of Appeals in 2004.⁸⁸ However, the Board did not rectify the decision and referred four questions to the Enlarged Board of Appeal (EBA).⁸⁹ The first question is procedural and concerns the effective time of Rule 28(c).⁹⁰ Regardless of the answer to that question, the requirements of Article 53(a) should be met beyond Rule 28(c).⁹¹ The second and third questions referred to the main issue in the case: the patentability of inventions involving the destruction of human embryos. The core argument in the case related to the proper approach for interpreting the phrase “use human embryos for industrial or commercial use.”⁹² The fourth question related to whether the decision in this case was binding when the method for which the patent was sought was capable of being accomplished without destroying human embryos as of the filing date.⁹³

In 2008, the EBA answered the four questions and decided that no patent

following: . . . c) uses of human embryos for industrial or commercial purposes”).

85. *Use of embryos/WARF*, 5 *OJ EPO* at 309.

86. Eur. Pat. App. No. 96,903,521 published as EP0770125.

87. *Use of embryos/WARF*, 5 *OJ EPO* at 327-28.

88. *Id.*

89. *Id.* at 307-08 (stating that four questions are: “(1) Does Rule 28(c) EPC extend to patent applications whose claimed subject-matter comprises a product derived from human embryos? (2) If the answer to question 1 is yes, does Rule 23d(c) [now 28(c)] EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims? (3) If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims? (4) In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: e.g. derivation from available human embryonic cell lines)?”).

90. *Use of embryos/WARF*, G 2/06 [2009] 5 *OJ EPO* 306.

91. *Id.* at 321-22 (noting that Rule 23d(c) contains the same wording as Article 53(a) EPC, which took effect in 1973).

92. Ewan Nettleton, *EPO’s Enlarged Board Rules on Patenting Stem Cell Inventions*, 4 J. INTELL. PROP. L. & PRAC. 306, 307 (2009).

93. *Use of embryos/WARF*, G2/06 [2009] 5 *OJ EPO* 306.

would be granted on inventions related to the destruction of human embryos.⁹⁴ First, the EBA affirmed that Rule 28(c) is retroactive to patent applications prior to enforcement.⁹⁵ Second, the EBA stated that the rationale underlying Rule 28(c) is “the prohibition of the misuse or commodification of embryos.”⁹⁶ The exclusion of Rule 28(c) listed in Recital 42 of the Directive applies only when human embryos are used for a “therapeutic or diagnostic purpose.”⁹⁷ The EBA further held that legislators deliberately declined to provide either a precise definition or a restricted interpretation of the term “embryo.”⁹⁸ With respect to the appellant’s allegation that the claim does not cover human embryo destruction, the EBA identified the term used in Rule 28(c) as an “invention,” not a “claim.”⁹⁹ The HESC derivation method disclosed in the description involved the destruction of the embryo.¹⁰⁰ Since the destruction of the embryo is an “essential and integral” part of the invention, the use of the human embryos is for “industrial or commercial exploitation.”¹⁰¹ The appellant attempted to defend its destruction of human embryos as not for “industrial or commercial use.”¹⁰² However, the EBA disagreed and noted that human embryo destruction is one step of the manufacturing procedure described in the claim.¹⁰³ Creating an invention that inevitably destroys

94. *Id.*

95. *Use of embryos/WARF*, G 2/06 5 OJ EPO at 322.

96. *Id.* at 323-24.

97. *Council Directive No. 98/44/EC*, 1997 O.J. (L 213) 13, 16 (providing that “whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes that are applied to the human embryo and are useful to it”).

98. *Use of embryos/WARF*, 5 OJ EPO at 325.

99. *Id.* at 326 (stating that “this Rule (as well as the corresponding provision of the Directive) does not mention claims, but refers to “invention” in the context of its exploitation. What needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed. Before human embryonic stem cell cultures can be used they have to be made. Since in the case referred to the Enlarged Board the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention falls under the prohibition of Rule 28(c)”).

100. *Id.* at 327 (finding that the destruction of the human embryo under the derivation method is an integral and essential part of the industrial or commercial exploitation of the claimed invention and thus violates the prohibition of Rule 28(c)).

101. *Id.*

102. *Id.*

103. *Id.* at 329 (“[I]t is important to point out that it is not the fact of the patenting itself that is considered to be against the ordre public or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts.”); see *Council Directive No. 98/44/EC*,

human embryos is one type of commercial exploitation. The patentability criteria apply to all steps of inventions. Since the invention covered the step that involved the destruction of human embryo, the patent application was rejected for its violation of the morality provisions.¹⁰⁴ Third, the EBA indicated its decision had no influence over the patentability of general inventions relating to human stem cells or human stem-cell cultures.¹⁰⁵

This case represents a rare instance in which an appellant requested the European Patent Convention (EPC) refer a patent question to the European Court of Justice (ECJ) for the reason that Rule 28(c) is the same as Article 6(2)(c) of the Directive.¹⁰⁶ It is rare because “the Boards of Appeal of the EPO are not courts or tribunals of a member state of the EU, and there is no power under the EPC for a Board of Appeal to refer questions to the ECJ.”¹⁰⁷ However, neither the EPC nor the Implementing Regulations grant any authority to refer questions of law to the European Court of Justice.¹⁰⁸ The conjunction of Rule 28(c) of EPC with Article 6(2)(c) of the Directive did not compel the conclusion that “the European Court of Justice now has jurisdiction to decide matters for the European Patent Office under the European Patent Convention.”¹⁰⁹ The Biotechnology Directive should be used by the EPO only as a supplementary method of interpretation, not as a direct source.¹¹⁰ Therefore, the EBA believed that the EPO should not seek ECJ guidance.

The EBA’s decision has had a significant and profound influence on the field of HESC research. It has removed doubt on some fundamental issues and built a foundation of legal certainty for Rule 28(c).¹¹¹ It unveiled the

1997 O.J. (L 213) 39 (“Whereas ordre public and morality correspond in particular to ethical or moral principles recognized in a member state, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention.”).

104. See *Use of embryos/WARF*, G 2/06 [2009] 5 OJ EPO 306.

105. *Id.* at 312.

106. See Rule 28 of EPC (providing that “under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes”).

107. *WARF*, G2/06 at 6.

108. *Id.* G2/06 at 3.

109. *Id.* at 6.

110. *Id.*

111. *Min*, *supra* note 33.

moral dilemma in patentability of HESC-related inventions and leaves space for evaluating the scope of Rule 28(c).¹¹² Some scientists predicted that the decision would encourage European companies to develop new HESC technology because the old technology is not patentable.¹¹³

3. Oliver Brüstle v. Greenpeace: The decision by European Court of Justice on patenting HESC

The ECJ and the EPO have similar concerns regarding the patentability of inventions involving human-embryo destruction. In *Oliver Brüstle v. Greenpeace*,¹¹⁴ the ECJ addressed the same two questions as the *WARF* case—namely the definition of the term “human embryos” and the scope of “industrial or commercial use” under Article 6(2) of the Directive—before concluding that the invention was not patentable.¹¹⁵ The case involved a patent that had been overturned by the German Federal Patent Court.¹¹⁶ The patent claims did not cover the production of HESC, but its methods of obtaining the cells were inevitably related to human-embryo destruction.¹¹⁷ However, unlike the situation in *WARF*, the HESC in this case had been obtained from existing HESC lines, consistent with German Embryo Protection Act.¹¹⁸

On March 10, 2011, the court concluded that, regardless of whether the description contained any reference to the use of embryos, the invention is not patentable since the patent “necessitates the prior destruction of human embryos.”¹¹⁹ The decision, authored by Judge Bot, appears to bring trouble

112. See, e.g., Pierre Treichel, *Case Comment G2/06 and the Verdict of Immorality*, 40 INT’L. REV. INTELL. PROP. & COMPETITION L. 450, 450 (2009) (positing an interpretation of prohibiting patents for “all the possible variants of the prohibited inventions in different circumstances”).

113. See James Randerson, *Europe Rejects Patent Governing Use of Embryonic Stem Cells*, *The Guardian* (Nov. 27, 2008), <http://www.guardian.co.uk/science/2008/nov/27/embryonic-stem-cells-patent> (discussing the implication the decision has on companies that develop technologies based on human embryonic stem cells).

114. *Case C-34/10, Brüstle v. Greenpeace eV*, 200 E.C.R. I-09821 (2011).

115. See *id.* at 23 (outlining two of the main questions in the case in determining whether the invention is patentable).

116. *German Patent No. DE 19756864 C5*.

117. See *id.* (claiming the isolation and purification of precursor cells generated from embryonic stem cells and explaining that embryonic stem cells emerge from pluripotent stem cells in the very early stages of the development of a fetus).

118. *The Embryo Protection Act*, *Federal Law Gazette*, pt. 1 no. 69 (1991); see also Jan P. Beckmann, *On the German Debate on Human Embryonic Stem Cell Research*, 29 J. MED. & PHIL. 603-21 (discussing Germany’s allowance of HESC research based on the existing HESC lines).

119. *Case C-34/10, Brüstle v. Greenpeace e.V.*, 8 (March 10, 2011),

beyond the patentability issue.¹²⁰ For example, the ruling might encourage other countries to adopt restrictive approach or total bans on the research.¹²¹ Some scholars have commented that the decision is too restrictive.¹²² They further state that without patent protection, the medical stem-cell industry will lose its incentive to develop HESC-based therapies.¹²³ Some existing achievements, developed through research under the European Commission and various EU member states, would also be nullified by a ban on patentability.¹²⁴ Finally, these commentators express hope that the ECJ's Grand Chamber "deliberate on the full implications before making a legally binding ruling."¹²⁵

The ECJ's Grand Chamber ruled against patentability on October 18, 2011.¹²⁶ The ECJ held that even already-existing HESC have been harvested from human embryos.¹²⁷ Therefore, inventions involving either newly derived HESC or HESC obtained from established stem cell lines are excluded from patentability.¹²⁸ Moreover, "use for industrial or commercial purposes" under Article 6(2) includes the use of human embryos for scientific research.¹²⁹ Austin Smith,¹³⁰ who wrote a letter criticizing the March 10th decision, complained that, "we are funded to do research for the public good, yet prevented from taking our discoveries to

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=81836&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=99614>.

120. *Id.* (stating that "the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes [set out in Article 6(2)(c) of the Directive 98/44] also covers the use of human embryos for purposes of scientific research," only use of therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable).

121. See Alison Abbott, *Europe Rules Against Stem-Cell Patents: Work with Human Embryonic Stem Cells is 'Contrary to Ethics'*, 471 NATURE 280, 281 (2011).

122. See *id.* at 281 (remarking that the opinion placed too much emphasis on cell-line origin and thus ignored the time at which a line has been established).

123. *Id.*

124. Austin Smith, *No to Ban on Stem Cell Patents* 472 NATURE 418 (2011) (listing drug development and cell-replacement therapy as examples of achievements that would be nullified by a ban on patentability).

125. *Id.*

126. *Case C-34/10, Brüstle v Greenpeace*, 2011 E.C.R. I-9849, I-9876-77 (holding that "the exclusion from patentability concerning the use of human embryos . . . also covers the use of human embryos for the purposes of scientific research").

127. *Id.*

128. *Id.*

129. *Id.* at I-9877 (holding that only uses for therapeutic or diagnostic purposes are not barred from patent under Article 6(2)).

130. See Smith, *supra* note 125 (Austin Smith is affiliated with the Wellcome Trust Centre for Stem Cell Research at the University of Cambridge).

the market place where they could be developed into new medicines.”¹³¹ The verdict might have the unfortunate effect of driving stem cell scientists out of Europe and blocking the development of some therapies derived from stem cells.

From the *Brüstle* ruling, we can conclude that the EU has erected a barrier to patenting HESC-related inventions. Moral considerations are deeply rooted in the EU—even in the UK, which has liberal policies towards HESC research.¹³² Despite the huge efforts made in the HESC regulations, there remains an inconsistency related to whether a moral examination is properly an element of patent law.¹³³ The ECJ and the EPO’s dual system of assessing morality standards has resulted in legal uncertainty. Therefore, we should reconsider how far patent law can accommodate the morality issues. This article argues, the EPO should not take the responsibility of examining the morality of HESC inventions: it would be better to leave such decisions to the Ethics Committee.¹³⁴

II CHINA: INCONSISTENT MORAL STANDARDS BETWEEN PATENT LAW AND PRACTICAL APPLICATION

Compared to the EU, China’s policy on HESC-related research and applications is relatively liberal and supported by Chinese culture and values.¹³⁵ Because the Chinese people have reached a consensus that abortion is legal, in China, embryos are not typically treated as persons.¹³⁶

131. Emma, *European Court Bans Stem-Cell Patents*, EURO STEM CELL (Oct. 18, 2011) <http://www.eurostemcell.org/node/21554>.

132. See Department of Health & Social Security, REPORT OF THE COMMITTEE OF INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY (“The Warnock Report”) (1984), available at <http://www.hfea.gov.uk/2068.html> (providing a dissenting view from those in the UK who believe the human embryo has a special status and should not be used for research.). But see Aurora Plomer, *Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the UK*, 10 MED. L. REV. 132, 133 (2002) (“The UK currently stands alone in Europe in permitting the creation of human embryos specifically for research purposes, including the use of cloning techniques.”).

133. See Laurie, *supra* note 2, at 61 (“[D]espite the fact that disquiet and discussions of an ethic nature held up the adoption of the biotechnology Directive for so long, it is far from clear that we are any further forward in developing uniform, logical, principled and defensible ethical guidelines within European patent law.”).

134. Ethical committee should involve individuals from diverse backgrounds who support HESC research with three major functions: providing clinical ethics consultation, developing or revising policies on HESC research, and monitoring research and clinical ethics.

135. Döring, *supra* note 15, at 236 (stating that “[t]he Chinese believe in the importance of individual autonomy, but they also believe that this right of autonomy is guided by social needs”).

136. Fu Jun Ying & Zhao Yun Hua, *Analysis of Related Policy, Funds and Outputs on*

Generally, human embryo use is not considered to be immoral by the Chinese.¹³⁷ However, similar to the EPC, the Patent Law of the People's Republic of China (PRC) also contains a moral prohibition.¹³⁸ Specifically, Article 5 of the PRC states that "patent right shall not be granted for invention-creations that violate the law or social ethics, or harm public interests."¹³⁹ According to the Commission on Legislative Affairs, the social morality standard depends on public acceptability.¹⁴⁰ If an invention is accepted by the public and allowed under the moral standard, it can be patented.¹⁴¹ Conversely, inventions such as artificial human organs for non-medical use and human-animal hybrid embryos are non-patentable for morality reasons.¹⁴²

A. Whether Article 5 of the patent law excludes inventions related to HESC?

As shown by the following analysis, HESC differentiation and culturing methods are both prohibited by the patent law. In addition, preparations of pre-implantation embryo for therapeutic cloning use are not patentable. However, inventions related to existing HESC lines are not contrary to morality under the Article 5 of Patent Law.¹⁴³

1. Advanced Cell Technology related to the differentiation of HESC and its culture method: lacking the explanation of "embryo" and "industrial or commercial purpose"

Advanced Cell Technology's¹⁴⁴ January 24, 2005 patent application

Stem Cells in China, 15 J. CLINICAL REHABILITATIVE TISSUE ENGINEERING RESEARCH 256, 257 (2011).

137. Liu Lidong, *Analysis of the Possibility Apply for Patent of Human Embryonic Stem Cell*, 30 HOSP. MGMT. FORUM 9, 11 (2013).

138. See Article 5 of Patent Law of the People's Republic of China (promulgated by Standing Comm. Nat'l People's Cong., Dec. 27, 2008, effective Oct. 1, 2009), available at <http://www.wipo.int/wipolex/en/details.jsp?id=6511>.

139. *Id.*

140. *The Development and Morality of Human Embryonic Stem Cell*, The State Intellectual Property Office of P.R.C, available at http://www.sipo.gov.cn/mjji/2006/200804/t20080401_362185.html.

141. *Id.*

142. See generally Part II Chapter 1, *Guidelines for Patent Examination*, State Intellectual Property Office, People's Republic of China (promulgated by the Standing Comm. Nat'l People's Cong., Jan. 21, 2010, effective Feb. 1, 2010), available at <http://www.wipo.int/wipolex/en/details.jsp?id=6511> (listing types of inventions for which no patent can be granted).

143. See *id.*; see also the patent law of People's Republic of China, available at http://www.sipo.gov.cn/zcfg/flfg/zl/fljxzf/200812/t20081230_435796.html.

144. See generally Company Overview, ACT: ADVANCED CALL TECHNOLOGY,

covered methods for improved cell-based therapies for retinal degeneration and for differentiating HESC.¹⁴⁵ Initially, the claims covered the differentiation of HESC into retinal pigment epithelial cells used to treat retinal degeneration.¹⁴⁶ Under Article 5, the patent could not be granted unless it deleted that claim.¹⁴⁷

A similar situation also occurred in the context of Beijing University's May 17, 2006 patent application related to a method for culturing HESC in a special culturing medium.¹⁴⁸ The patent applicant deleted claims involving HESC culturing before the patent was granted.¹⁴⁹ Likewise, the authorization of a patent application covering methods of preparing feeder-cell-free, xeno-free HESC and stem-cell cultures specified the elimination of the HESC culturing methods that had been included in the applicant's public specification.¹⁵⁰

It is well established in this case that patent could not be granted to the differentiation of HESC and its culture method. However, neither "embryo" nor "industrial or commercial purpose" were defined in this case. Although the Chinese Patent Office encountered the same problems as the European Office,¹⁵¹ it neither provided any explicit explanation nor offered

<http://www.advancedcell.com/about-act/company-overview/> (last visited July 15, 2014) (giving background on Advanced Cell Technology, Inc., a biotechnology company that specializes in the development of cellular therapies using stem cell-based technologies).

145. Patent Application No. CN 1968608 A, May 23, 2007, available at <http://www.google.com/patents/CN1968608A?cl=en> (claiming methods for improved cell-based therapies for retinal degeneration and for differentiating HESC and human embryo-derived retinal cells).

146. *Id.*

147. *Id.*

148. Patent Application No. CN 1844374 A, May 17, 2006, available at <http://www.google.com/patents/CN1844374A?cl=fr> ("Culture method for human embryonic stem cell and special culture medium thereof").

149. *Id.*

150. Patent Application No. CN 100549163C, Oct. 14, 2009, available at <http://www.google.com.tr/patents/CN100549163C?cl=zh-CN> (relating to the use of feeder cells for the method of propagating a culture system and a human embryonic stem cell line); Patent Application No. CN 1748025A, Mar. 15, 2006, available at <http://www.google.com.tr/patents/CN1748025A?cl=zh-CN> (claiming a method of preparation of feeder cells-free, xeno-free human embryonic stem cells and stem cell cultures).

151. Brian Salter, *Governing Stem Cell Science in China and India: Emerging Economics and the Global Politics of Innovation*, 27 NEW GENETICS & SOCIETY 145, 154 (2008) (stating that with its accession to the World Trade Organization (WTO) in 2001, China agreed to conform to the requirements of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Since then China has cooperated frequently with the World Intellectual Property Organization (WIPO) and the European Patent Office (EPO) on personnel training and promoted IPR teaching and research in over seventy universities); *see*

any approach for future judgment.

2. Shanghai Genon Biological Product: HESCs with the possibility of developing into human being are within the scope of “human embryo”

On November 2 1999, Shanghai Genon Biological Product Co. Ltd.’s (“Genon”) patent referred to the preparation of pre-implantation embryos for therapeutic cloning use.¹⁵² The publication date of the patent application was July 11, 2001.¹⁵³ In 2003, the PRC’s Intellectual Property Office (IPO) rejected the application pursuant to Article 5. The decision was made for the several reasons. First, the method used in the invention involved mixing a donor nuclear cell and non-mammal cytoplasm derived from donor oocytes. The reconstructed cell is stimulated and transplanted into non-human mammals.¹⁵⁴ Finally, the cell is developed into early embryos, which is contrary to the morality provisions under the Article 5. The IPO held that because the cell contains complete genetic information, the early embryo should be identified as a human embryo. The preparation method for an early embryo is equivalent to human cloning. Therefore, the invention falls within the moral exclusion of Article 5.¹⁵⁵ Second, the IPO held that the invention was for industrial and commercial purposes, and therefore violated Article 5.¹⁵⁶ Third, as stated in the patent claim, the

also Tang Huadong and Wang Dapeng, *The Analysis of the Patentability of Human Embryonic Stem Cell*, 5 INTELLECTUAL PROPERTY 52, 54 (2013).

152. Shanghai Genon Biological Product Co. Ltd. became the high and new technology enterprise in Shanghai, Little Giant Breeding enterprise, important enterprise of feed industry in Shanghai and the main unit which drafts out the national standard of “[s]pray dried globin protein powder for feed.” The company has taken on a large number of special government projects such as an industrialization project of high and new technologies from National Development and Reform Commission, National Spark Plan, an innovation fund for medium and small enterprise, domestic cooperation projects in Shanghai, which “develop agriculture by science and technology projects” in Shanghai, and “four news” technology projects in Shanghai, available at <http://www.cngenon.com/>

153. CN 99119951.0, available at <http://www.pss-system.gov.cn/sipopublicsearch/search/searchHome-searchIndex.shtml?params=991CFE73D4DF553253D44E119219BF31366856FF4B152226CAE4DB031259396A>.

154. See The 5972 re-examination decision by the patent review committee, available at http://app.sipo-reexam.gov.cn/reexam_out/searchdoc/decidedetail.jsp?jdh=FS5972&lx=fs; see also Wu Zhou Min, The 5972 Re-examination Decision by the Patent Review Committee-the Preparation of Pre-implantation Embryos for Therapeutic Cloning Use, available at <http://www.bioipr.com/biopharma-ipr/1108/>.

155. *Id.*

156. Wu Zhou Min, *The 5972 Re-examination Decision by the Patent Review Committee- the Preparation of Pre-implantation Embryos for Therapeutic Cloning Use*, available at <http://www.bioipr.com/biopharma-ipr/1108/>.

resulting embryo would be a human-animal hybrid, which is forbidden by the patent-examination guidelines.¹⁵⁷

In 2004, Genon appealed to the patent review committee making several arguments. First, although the embryo includes human genetic information, the embryo is a human-animal hybrid, not a human embryo. Thus, the invention is not related to the industrial or commercial use of a *human* embryo.¹⁵⁸ Second, the embryo created by this method has no possibility of becoming human because claims 1-10 of the application contain no human-cloning steps.¹⁵⁹ Third, the invention represented one aspect of human organ transplantation technology.¹⁶⁰ Therefore, the invention is properly classified as therapeutic cloning. Neither its aim nor its method involved human cloning. In conclusion, the invention did not contravene the law, morality, or the public interest.¹⁶¹

Yet the committee reexamined the patent application and concluded that the invention is unlawful based on Article 5 for two reasons.¹⁶² First, the nuclei donor's genetic information had a decisive impact on the cell's overall performance. Genon's patent application contained human nuclei materials that possessed the characteristics of human cells.¹⁶³ As claimed in the patent application, the invention is primarily used for the purpose of tissue or organ transplantation. If so, the invention could not exclude the possibility of developing into a human being. However, the committee did not ignore the possibility that the embryonic cells could exhibit the characteristics of an animal.¹⁶⁴ In that situation, the method still violates public morality because it changes the genetic identity of a human germ line. Second, the claim does not exclude the possibility of the early embryos developing into humans. Genon did not provide any evidence to prove that the embryos could not develop into human being.¹⁶⁵ It has been speculated that HESC has the legal status of human being since HESC comes with the possibility of developing into human being. Therefore, the inventions related to HESC are against public morality under Article 5 of patent law. The argument in this case seems to provide an interpretation of "human embryo." However, many ambiguous aspects remain, especially in

157. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*; see also Liu Lidong, *Analysis of the Possibility Apply for Patent of Human Embryonic Stem Cell*, 30 HOSPITAL MANAGEMENT FORUM 9, 11 (2013).

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

how broadly or narrowly to construe the possibility of HESCs developing into a human being.

3. Case the Regents of the University of California: It is improper to trace the origin of the world's first HESC lines; therefore, established stem cell lines are allowed

The next patent application that we consider was filed by the Regents of the University of California in 2003 and covered oligodendrocytes derived from HESC for remyelination and the treatment of spinal-cord injuries.¹⁶⁶ The IPO held that this invention violated Articles 5 and 22 of the PCR.¹⁶⁷ The committee believed that the patent specification and claims in their entirety related to HESCs obtained from human embryos, thus violating social morality through the use of human embryos for industrial or commercial purposes. In addition, the pluripotent cell derived from non-embryonic tissue required bone marrow or other human or animal tissues through a surgical method for non-therapeutic purposes. Thus, the invention could not satisfy the utility standard set forth in Article 22.¹⁶⁸

The applicant appealed to the patent review committee on the following two grounds. First, the HESC aspect of the invention had been removed from the patent specification, and the cell lines used in the invention belong to established, mature, already-commercialized HESC lines.¹⁶⁹ Second,

166. See the 42698 re-examination decision of the patent review committee, *available at* http://app.sipo-reexam.gov.cn/reexam_out/searchdoc/decidedetail.jsp?jdh=42698&lx=fs.

167. Patent Law of the People's Republic of China (promulgated by the Standing Comm. of the Seventh Nat'l People's Cong., Sept. 4, 1992, effective January 1, 1993) Article 5 <http://www.chinatradoemarkoffice.com/about/laws2.html#2> (providing that "No patent right shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to public interest."); Patent Law of the People's Republic of China (promulgated by the Standing Comm. of the Seventh Nat'l People's Cong., Sept. 4, 1992, effective January 1, 1993) Article 22 <http://www.chinatradoemarkoffice.com/about/laws2.html#2>. ("Any invention or utility model for which patent right may be granted must possess novelty, inventiveness and practical applicability. 'Novelty' means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publications in the country or abroad or has been publicly used or made known to the public by any other means in the country, nor has any other person filed previously with the patent office an application which described the identical invention or utility model and was published after the said date of filing. 'Inventiveness' means that, as compared with the technology existing before the date of filing the invention has prominent substantive features and represents a notable progress and that the utility model has substantive features and represents progress. 'Practical Applicability' means that the invention or utility model can be made or used and can produce effective results.").

168. *Id.*

169. *Id.*

the application's claims explicitly excluded direct decomposition from the human-embryo or HESC-related technology solution. In addition, the application had deleted all industrial or commercial uses of human embryos.¹⁷⁰

With respect to Article 5, the applicant argued that the origin of HESC lines should not be traced in perpetuity.¹⁷¹ The starting material of the application consisted of established HESC lines capable of unlimited in vitro proliferation. In the prior art, there are many ways to obtain mature and stable HESC lines. Moreover, it is improper to trace the origin of the world's first HESC lines. Using established HESC lines could decrease human-embryo abuse and in turn, limit the use of HESCs to mature strains. Therefore, the application does not violate Article 5's social-morality provision.¹⁷²

The board recognized that it is inappropriate to trace the origin of HESC lines, and that using established stem cell lines is allowed by the morality provisions in the patent law. However, in the following decision 24343 made by the Patent Reexamination Committee, the committee held that although HESCs could be obtained from commercial channels, the source of HESCs still rely on the destruction of the human embryo.¹⁷³ More definitively, the culture of HESCs had significant problems like being time-consuming, difficult to operate, and easy to contaminate. As a result, established cell lines are not the steady and long-term source of HESC. Subsequently, the argument that using established HESCs could end the destruction of human embryo was unrealistic.¹⁷⁴

The uncertainty decision promulgated by the Patent Office is due to the misunderstanding of the moral provision.¹⁷⁵ The moral standard as well as the relevant definition should be clarified and developed as soon as possible.

170. *Id.*

171. *Id.*

172. *Id.*

173. The 24343 re-examination decision of the patent review committee, *available at* http://app.sipo-reexam.gov.cn/reexam_out/searchdoc/decidedetail.jsp?jdh=FS24343&lx=fs.

174. *Id.*

175. See Warren-Jones, *supra* note 52, at 660 (observing that the lack of consensus in the suppliance of the morality provision suggests that there is a fundamental misunderstanding regarding the definition and application of the provision. The closer this analysis gets to achieving an operative understanding of the provision, the greater recourse to commentators to bridge the gaps in practice).

B. Low moral status of human embryos in practical application

Contrary to popular assumptions, Chinese people place value on life.¹⁷⁶ Based on Confucian philosophy, life begins at birth.¹⁷⁷ A human embryo holds the status of a pre-human being. Accordingly, the moral status of a human embryo is not equal that of a human-being. Moreover, abortion is not prohibited and is sometimes compulsory under China's "one-child policy."¹⁷⁸ A survey about the moral status of HESC research carried out in hospitals shows that more than fifty percent of doctors believe that human embryos are not human beings and that more than seventy percent of doctors support HESC research.¹⁷⁹ Under China's civil law, civil rights begin at birth.¹⁸⁰ A fetus is not a legal entity: in other words, fetuses are not human-beings.

Therefore, China's moral standards are very different from those of Western countries. Even considering the existence of varying local circumstances, China has a much lower moral standard related to HESC research than do Western countries.¹⁸¹

C. High moral status of the human embryo in patent law

The first edition of China's patent law was drafted with reference to the patent law of other countries, particularly the UK.¹⁸² Article 5 of the Patent

176. Achim Rosemann, *Life Without Value? Voices of Embryo Donors for hESC Research in China*, IIAS NEWSLETTER (Winter 2009), at 17 (concluding that "[e]qually flawed appears the assumption that due to the high number of abortions carried out in the context of the one-child policy, the value of early forms of human life are generally of low regard among Chinese people.").

177. Han Xin, *The Ideological of Confucius*, available at <http://www.confuchina.com/10%20lishi/kongzi%20sixiang.htm>.

178. Jing-Bao Nie, *Behind The Silence. Chinese Voices On Abortion* 100, 104 (2005).

179. Qiu Xiang Xing, Gao Zhi Yan, Wang De Yan, Wang Ming Xv, Shen Ming Xian and Chen Ren Biao, A SURVEY AND DISCUSSION ON ETHICAL ISSUES OF HUMAN EMBRYONIC STEM CELL RESEARCH, 1 MED. & PHILO. 8 (2004).

180. See General Principles of the Civil Law of the People's Republic of China (effective January 1, 1987) Article 9 P.R.C. Laws (providing that "[a] citizen shall have the capacity for civil rights from birth to death and shall enjoy civil rights and assume civil obligations in accordance with the law").

181. See Margaret E. Sleeboom-Faulkner, *National Risk Signatures and Human Embryonic Stem Cell Research in Mainland China*, 12 HEALTH, RISK & SOC'Y 491, 496-97 (2010) (describing that "[w]hen in 2001 President Bush announced a moratorium on the federal funding of stem cell research, China, as some other countries in Asia (India, Singapore, South Korea, Japan and Taiwan), denied any engagement with the ethics that had informed the decision. In fact, they were ready to jump into the bioethical vacuum it had created. This vacuum was alleged to be a result of Western moral scruples about using fertilised human cells, allegedly absent in the East.").

182. Wei Dong, *Study on Patentability of Human Embryonic Stem Cell Related*

law of P.R.C. is the same as Article 53 of the European Directive.¹⁸³ Additionally, in the later revision to the patent law, Article 5 was not substantially modified. Is it proper to include a moral exclusion in the patent law though? This article takes the view that patent law should not be used as a tool to prohibit unethical research because the law's primary goals are to protect inventions and encourage creation. The principles and clauses contained in the patent law should represent the spirit of that law. With respect to moral exclusions, HESC research could still be continued or sponsored in the absence of patent protection for the resulting products.¹⁸⁴ For example, in China, unverified stem cell therapy could be carried out in the clinics and hospitals.¹⁸⁵

Although China's moral standards seem to be lower than those of Western countries in practical application, according to the patent-examination guidelines, it is forbidden to patent the use of embryos for commercial or industrial purposes.¹⁸⁶ As in Europe, the Chinese patent regulations contain no direct definition of "embryo" or "commercial or industrial purpose." Thus, the Chinese patent office has encountered the same problems as the European office. However, unlike Europe, Chinese regulators have not needed to consider the issue of conflicting moral standards among member states.

Since China's moral standards on this issue are much lower than those in Europe,¹⁸⁷ it is likely that Chinese regulators have adopted the moral exclusion in patent law primarily due to the belief that it represents an international custom. In response to pressures from stem cell markets, some scientists from countries with restrictive policies will rush areas that

Inventions, East China University of Political Science and Law, master thesis (2011).

183. European Directive 98/44/EC on Biotechnology.

184. See Laurie, *supra* note **Error! Bookmark not defined.**, at 64 (stating how one may argue that the absence of patent protection may discourage research but not researching would be an inefficient manner to tackle moral concerns and thus research will continue).

185. See Lianming Liao & Robert Chunhua Zhao, *An Overview of Stem Cell-Based Clinical Trials in China*, 17 STEM CELLS & DEV. 613, 615 (2008) (reporting that "the Fourth Military Medical University of China further used peripheral blood monocytes that had been induced to differentiate into functional hepatocytes in vitro to treat patients with hepatitis B virus (HBV)-related decompensated liver cirrhosis"); see also Haidan Chen, *Stem Cell Governance in China: From Bench to Bedside?*, 28 NEW GENETICS & SOCIETY 267, 2274 (2009) (reporting that "Beike Biotech was set up in Shenzhen, the first special economic zone of China on 18 July 2005. It collaborates with hospitals and treats patients in the hospitals and then shares the resulting profit. Until 2008 Beike cooperated with thirteen hospitals; six centers were added in 2008, and five new centers will be initiated in 2009").

186. GUIDELINES FOR PATENT EXAMINATION, STATE INTELLECTUAL PROPERTY OFFICE, PEOPLE'S REPUBLIC OF CHINA.

187. See Liu Lidong, *supra* note 162.

have permissive policies or alternatively, some might engage in the activities conducted in more permissive areas. Likewise, Chinese scientists and doctors will blur what can and cannot be done due to a lack of medical risks or moral concerns. HESC research involving therapeutic cloning and other sensitive procedures cannot be effectively monitored, resulting in “biomedical adventurism”¹⁸⁸ that could create a nightmare for the entire legal and social infrastructure.

Therefore, it would be more appropriate or effective to issue a specific regulation related to moral standards for HESC research. Any invention permitted by that specific law should be patentable. Immoral research should be forbidden from the beginning instead of at the patent-application stage.¹⁸⁹ Moreover, from an economic point of view, restricting immoral research from the beginning could save a tremendous amount of time and money. It would be more effective to implement specific legal regulations applicable to HESC research than to include a general moral exclusion in the patent law.

III. THE UNITED STATES: INCONSISTENT POLICIES ON FEDERAL FUNDING CONTROL OF HESC RESEARCH

In the U.S., regulation of HESC research primarily centers on federal funding control, not moral control. The story of HESC regulations in the U.S. involves a battle between the executive and judicial branches, along with a battle between federal and state government.¹⁹⁰ For decades, the primary moral concern addressed by HESC regulation involved whether an embryo is a legal person.¹⁹¹ Unlike in the EU and China, U.S. patent law does not contain a moral exclusion. According to *Juicy Whip, Inc. v. Orange Bang*, the United States Court of Appeal for the Federal Circuit held that the Patent Office should not play a role in determining whether an invention is moral.¹⁹² In 1980, however, the United States Supreme Court

188. Doring, *supra* note 17, at 42 (commenting that the positivistic principle “if an action is not illegal, by definition, it is legal” does not apply in China. Taking advantage of the fact that policymaking lags behind scientific and economic development, in terms of the entire legal and social infrastructure, amounts to biomedical adventurism).

189. Zhu Huan, *Patentability of Embryonic Stem Cells Related Inventions*, East China University of Political Science and Law, Master’s Thesis (2008).

190. See Owen C. B. Hughes, Alan L Jakimo and Michael J. Malinowski, *United States Regulation of Stem Cell Research: Recasting Government’s Role and Questions to be Solved*, 37 HOFSTRA L. REV. 383 (2008) (overview of the development of U.S. law on stem cell research).

191. G. Bahadur and M. Morrison, *Patenting Human Pluripotent Cells: Balancing Commercial, Academic and Ethical Interests* 25 HUMAN REPRODUCTION 14-21 (2010).

192. *Juicy Whip, Inc. v. Orange Bang*, 185 F.3d 1364 (Fed. Cir. 1999) (finding that a beverage dispenser that simulated a fake display of churning juice, when the juice was not in

opened the door to grant patents on “non-naturally occurring living substances” in *Diamond v. Chakrabarty*.¹⁹³ Since then, thousands of genes, animals, and other organic materials have been the subjects of patent protection.

*A. Wisconsin Alumni Research Foundation (WARF): the opening of
“human embryo farms”*

The focal points of world debate on the issue of HESC are three fundamental patents held by the Wisconsin Alumni Research Foundation (“WARF”). In 1998, after James Thomson published work on the isolation of embryonic stem cell lines, WARF (as his representative) applied to the USPTO to patent that work. Three basic patents, known as the 780, 806 and 913 patents, were issued.¹⁹⁴ The claims of these patents are quite broad.¹⁹⁵ Patents 780 and 806 claim product embryonic cells. Patent 913 claims both product embryonic stem cells and the method of obtaining them.

WARF holds a fee-based and royalty-bearing license to make, use, and sell HESC lines. WARF has been widely criticized for its restrictive policy towards educational and scientific institutions.¹⁹⁶ In the commercial area, WARF transferred an exclusive license to Geron to develop products derived from the patents. Because the patents cover broad HESC technology, any commercial potential is restricted to exploitation by

fact fresh lacked utility and was therefore unpatentable).

193. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (upholding application asserting thirty-six claims related to Chakrabarty’s invention of a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids). The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. *Id.* His decision rested on two grounds: (1) that micro-organisms are products of nature and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101. *Id.*

194. United States Patent No. 5,843,780, December 1, 1998 (covering a purified preparation of primate embryonic stem cells); United States Patent, 6,200,806, March 13, 2001 (containing a purified preparation of pluripotent human embryonic stem cell); United States Patent, 7,029,913, April 18, 2006 (including a replicating in vitro cell culture of human embryonic stem cells comprising cells).

195. See K. Bergman and G.D. Graff, *The Global Stem Cell Patent Landscape: Implications for Efficient Technology Transfer and Commercial Development*, 5 NATURE BIOTECHNOLOGY 419, 419 (2007) (finding these patents are to be some of “the strongest intellectual property holdings in the whole stem cell field, establishing control at the very root of all possible lineages of cellular differentiation[.]”).

196. See Aurora Plomer, Kenneth S Taymor and Christopher Thomas Scott, *Challenges to Human Embryonic Stem Cell Patents*, 2 CELL STEM CELL 13, 13 (2008) (criticizing WARF for slowing distribution of cell lines and cast a shadow over the ability of researchers to advance knowledge).

Geron.¹⁹⁷

Although the three patents application were refused for reasons of moral concern by the EU, in the US, they were challenged for technical reasons. The Foundation for the Taxpayer and Consumer Rights, in conjunction with the New York-based Public Patent Foundation, challenged the patents on grounds of obviousness with respect to the prior art.¹⁹⁸ In addition, biomedical researchers worried that the USPTO's lax practices could stifle scientific innovation by granting patent holders overly broad rights over basic knowledge and research tools.¹⁹⁹ In response to concerns related to impeding scientific and economic progress due to the lack of guidelines for its patenting criteria, the USPTO received both oppositions.

Subsequently, WARF's patent application was appealed amidst intense criticism. One objection related to the cost and restrictiveness imposed on researchers by WARF's licensing practices.²⁰⁰ However, it is possible that, the reason for the high cost of HESC research is the patent licensing fees. For example, the Thomson patents allow WARF to demand money from anyone who wants to use its stem cells, thus increasing the cost of research and restricting that research to those who can afford to pay.²⁰¹ Critics have called WARF's approach to licensing "overly costly, cumbersome and restrictive."²⁰² Although opponents of HESC research have attempted to use the patent system to stop what they consider unethical research, there is little basis in the U.S. patent law for moral barriers against the WARF patents.²⁰³ It appears that one of the reasons that no explicit morality clause

197. *Rovert Lanza from Advanced Cell Technology in Worcester, Massachusetts, claimed that "we would be sued if we even tried to develop insulin-producing cells to treat diabetes."* Constance Holden, *US Patent Office Casts Doubt on Wisconsin Stem Cell Patents*, 316 SCIENCE MAGAZINE 182, 182 (2007).

198. Request for Ex Parte Reexamination of US Patent No. 5,843,780, Request for Ex Parte Reexamination of US Patent No 6,200,806, and Request for Inter Parties Reexamination of US Patent No 7,029,913.

199. David B Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15 HEALTH CARE ANAL 211-222 (2007).

200. See John M. Golden, *WARF's Stem Cell Patents and Tensions Between Public and Private Sector Approaches to Research*, 38 J. L. MED. & ETHICS 314, 315 (2010).

201. See Terry Devitt, *Wisconsin Scientists Culture Elusive Embryonic Stem Cells*, (Nov. 6, 1998) available at <http://www.news.wisc.edu/3327> (stating that finding ways to direct the human embryonic stem cells to become specific cells of clinical importance is an important next step required before new therapies can be developed).

202. See Golden, *supra* note 200, at 315 (stating the WARF's patents cover many HESC lines in the U.S. and have been used to assert control over many beyond the scope of the patent).

203. *Id.* (analyzing that U.S. patent law provides comparatively little basis for such a morality-oriented barrier to WARF's patents. Instead, challenges to WARF's patents in the United States have attacked the value of Thomson's scientific contribution).

exists in U.S. patent law is the lack of an intense debate and discussion in the U.S. over whether HESC should be considered patent-eligible subject matter.

B. Political interventions—the federal funding control of HESC research under moral concerns

It is necessary to have an overview of the core of U.S. political system—the social contract—before looking into the specific issue of HESC.²⁰⁴ With respect to HESC research, the question of whether stem cells are persons is not hotly debated in the U.S. Instead, the focus of the argument is whether federal funding should be granted for HESC research. Indeed, there are no federal regulations in the United States that restrict HESC research. On the contrary, control over HESC research relates to the allocation of federal funding.²⁰⁵ There are three levels of federal funding of HESC research: (1) complete prohibition, (2) limited prohibition, and (3) permission. For a long time, the government banned federal funding of any research that involved human embryos.²⁰⁶

However, in 1996, pursuant to Executive Order 12,975, the National Bioethics Advisory Commission (“NBAC”) was established to protect “the rights and welfare of human research subjects and issues in the management and use of genetic information.”²⁰⁷

NBAC’s establishment was a profound historical event in the regulation of HESC research because it “increased the awareness of U.S. and foreign governments, international groups, the research community, and the public about complex bioethical issues, thereby helping to provide a forum for public debate.”²⁰⁸ In the meantime, President Clinton required relevant

204. JEAN JACQUES ROUSSEAU, *THE SOCIAL CONTRACT*, 1-138 (1st ed., 2010) (stating that the social contract can be described as follows: “Each of us puts his person and all of his power in common under the supreme direction of the general will; and in a body we receive each member as an indivisible part of the whole”).

205. Christine Vestal, *Stem Cell Research at the Crossroads of Religion and Politics*, PEW FORUM PAPER (July 17, 2008), available at <http://pewforum.org/Science-and-Bioethics/Stem-Cell-Research-at-the-Crossroads-of-Religion-and-Politics.aspx>.

206. See PAUL MURRAY MCNEILL, *THE ETHICS AND POLITICS OF HUMAN EXPERIMENTATION* 119 (1st ed., 1993) (providing an overview of “balancing interests of researchers against the protection of the interests of subjects of human experimentation”); see also Kyla Dunn, *The Politics of Stem Cells*, NOVA SCIENCE NOW (Jan. 4 2005) available at <http://www.pbs.org/wgbh/nova/body/stem-cells-politics.html> (discussing the illegality of using federal funds for “any experiment that creates or destroys a human embryo”).

207. Exec. Order No. 12,975, 3 C.F.R. 1759 (1995).

208. EISEMAN ELISA, *THE NATIONAL BIOETHICS ADVISORY COMMISSION: CONTRIBUTING TO PUBLIC POLICY* 130 (1st ed., 2003).

executive agencies, within the NBAC, to report their opinions on developing human-subject-protection policies.²⁰⁹ Based on an NBAC report, President Clinton signed the “Cloning Prohibition Act of 1997” to ban the creation of babies through somatic cell nuclear transfer cloning.²¹⁰ Although the history of federal involvement in HESC research is quite complex, these events are distinguishable from the jurisdictional battle over federal regulation of HESC research.

1. The National Institutes of Health Revitalization Act: Allow Federal Funding of Research Related to Embryos at the Early Stage

The Department of Health and Human Services (“HHS”) is the chief U.S. government agency providing human services, granting federal research funds, and providing health insurance. HHS consists of eleven operating divisions. Among these divisions, the National Institutes of Health (“NIH”) is responsible for funding biomedical and health-related research. Initially, research related to human subjects was prohibited from receiving federal funds. In September 1988, the NIH Advisory Committee voted to lift the moratorium on the use of federal funds for fetal-tissue transplantation research.²¹¹ In 1993, President Clinton, supported by the NIH review panel, lifted the moratorium, and a congressional hearing followed.²¹²

Next, the National Institutes of Health Revitalization Act authorized federal funding of research involving human fetal tissue transplantation.²¹³ This Act also paved the way for federal funding of research related to early-stage embryos.²¹⁴ With the endorsement of the National Institutes of

209. Mary Leinhos, *The US National Bioethics Advisory Commission as a Boundary Organism*, 32 SCI. & PUB. POL. 423, 426 (2005) (“The Commission was granted the authority to deliberate on additional issues raised by the general public, other federal bodies and organizations, or NBAC itself.”).

210. *Id.* at 427 (stating that “[c]onsistent with the NBAC’s recommendation, the President’s legislative proposal contained a five-year prohibition on the use of somatic cell nuclear transfer to create human beings and directed the NBAC to report to the President after four and one-half years about whether to continue the ban.”).

211. NAT’L INSTS. OF HEALTH, HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH (1988).

212. Helen M. Maroney, *Bioethical Catch-22: The Moratorium on Federal Funding of Fetal Tissue Transplantation Research and the NIH Revitalization Amendments*, 9 J. CONTEMP. HEALTH L. & POL’Y. 485, 487 (1993).

213. *Research on Human Fetal Tissue Amendments Act of 1993*, 42 U.S.C. § 289g-1 note (2012).

214. *Doe v. Shalala*, 862 F. Supp. 1421, 1424 (1994) (commenting on the Act as follows: “This law [the Revitalization Act] amended existing federal regulations governing research on human embryos, which required such research to be reviewed by an EAB before such research might proceed. Because prior presidential administrations apparently chose

Health Revitalization Act, in 1994, the NIH set up the Human Embryo Research Panel to develop policies for the use of embryos and the moral scope of that research.

2. Dickey-Wicker Amendment: No Federal Funding on HESC Research Involving Destruction of an Embryo

Contrary to his previous position, President Clinton issued an executive order to ban federal funding of HESC research in the wake of a resounding Democratic electoral defeat.²¹⁵ In 1995, consistent with President Clinton's declaration, Congress overrode the decision to sponsor some types of stem-cell research. The Dickey-Wicker Amendment, named for Representatives Jay Dickey and Roger Wicker, was approved by Congress.²¹⁶ The Dickey-Wicker Amendment is a rider to other legislation concerning HHS. It is the first regulation to focus specifically on embryo research and is also the United States' most important regulation regarding HESC research. Subpart A of the Amendment reflects an endorsement of the existing prohibition on embryo creation. Parallel to Subpart A, Subpart B adds a ban on federal funding of any research involving embryos obtained from in vitro fertilization (IVF) procedures.²¹⁷ It is clear that research involved with the destruction of embryos is excluded from federal funding. However, the problem of research using already-destroyed embryos from IVF is still unsettled, which has led to debate.

Despite the lack of federal funding, HESC research has developed and flourished with private support. In 1998, scientists claimed that they had successfully derived stem cells from human embryos and emphasized the potential of stem cells to grow into specific cells.²¹⁸ Following this

not to appoint an EAB, no funding for such research had in fact been approved. What the new law did was to reverse the conditions for in vitro fertilization research: it could go forward unless disapproved. Previously it could not go forward unless approved").

215. Heather J Meeker, *Issues of Property, Ethics and Consent in the Transplantation of Fetal Reproductive Tissue*, 9 BERKELEY TECH. L. J. 185, 187 (1994) (citing profound ethical and moral questions associated with the subject, refused to follow the contrary recommendation of a National Institutes of Health panel).

216. Dickey Amendment, Pub. L. 111-8, § 509, 123 Stat. 803 (1996).

217. *Id.* (The Amendment's prohibitions read as follows: (a) None of the funds made available in this Act may be used for—(1) The creation of a human embryo or embryos for research purposes; (2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero. (b) For purposes of this section, the term 'human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells).

218. James A Thomson, *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145, 1145-46 (1998).

landmark development, on January 15, 1999, top HHS lawyer Harriet Rabb declared that the Dickey-Wicker Amendment should not apply to derived stem cells because such cells “are not a human embryo within the statutory definition.”²¹⁹ Therefore, HHS took the position that the NIH could provide federal funding to HESC research on the ground that a stem cell could not become an organism because it had not been implanted into a uterus.²²⁰

In response to the HHS opinion, the NIH appointed a group of experts to develop appropriate guidelines. Meanwhile, the notion that federal funds could be used for HESC research was backed by the Clinton administration.²²¹ However, seventy-seven Congressional opponents wrote two letters to the Secretary of HHS to criticize the provision allowing federal funding to HESC research.²²²

3. NIH Guideline 2000

Regardless of the National Institutes of Health Revitalization Act and the Dickey-Wicker Amendment’s contradictory interpretations, the NIH published a Guideline outlining funding-ineligible types of HESC research.²²³ The Guideline restricts the scope of federal funds to stem cells

219. See Letter from Harriet Rabb, Gen. Counsel, Dep’t of Health & Human Servs., to Harold Varmus, Director, NIH, (Jan. 15, 1999) (General Counsel Rabb determined that the statutory ban on human embryonic research defined an embryo as an “organism” that, when implanted in the uterus, is capable of becoming a human being); see also JUDITH A JOHNSON & ERIN D WILLIAMS, CRS REPORT: STEM CELL RESEARCH: FEDERAL RESEARCH FUNDING AND OVERSIGHT, 7 (Apr. 18, 2007) available at <http://www.fas.org/sgp/crs/misc/RL33540.pdf>.

220. Meredith Wadman, *Embryonic Stem Cell Research Exempt from Ban, NIH is Told*, 397 NATURE 185-86 (1999) (quoting an NIH official, “this opinion allows us to proceed carefully and thoughtfully with a line of research that has enormous potential for the treatment of almost every disease and condition”).

221. See Eliot Marshall, *Ethicists Back Stem Cell Research, White House Treads Cautiously*, 285 SCI. 502, 503 (1999).

222. Meredith Wadman, *Congress May Block Stem Cell Research*, 397 NATURE 639, 639 (1999) (The writer claimed that Rabb “makes a specious distinction by reading the law narrowly” to apply only to the act of destroying embryos, and not more broadly to include any research that depends on their destruction; Jay Dickey, the author of the existing ban, also stated that stem-cell derivation was “precisely the kind of research for which we intended to ban, and did ban, federal funding”).

223. Clinton administration NIH Guidelines for embryonic stem cell funding, 65 Fed. Reg. 51,975, Aug. 25, 2000. The Guidelines state that the following research areas are ineligible for NIH funding:

A. The derivation of pluripotent stem cells from human embryos; B. Research in which human pluripotent stem cells are utilized to create or contribute to a human embryo; C. Research utilizing pluripotent stem cells derived from human embryos created for research purposes, rather than for fertility treatment; D. Research in

derived from ‘human embryos created for the purposes of fertility treatment and exceeded the clinical need of the individuals seeking such treatment’.²²⁴ The Guideline also established a national review panel, the NIH Human Pluripotent Stem Cell Review Group.²²⁵

However, before the NIH could provide funding, the Bush Administration took power and conducted a legal review of Clinton-era policy. Implementation of the Guideline was halted and federal funding was never granted. Nevertheless, the Clinton Administration had already opened the door for federal funding of HESC research.²²⁶

4. The Bush Compromise accepted the narrow explanation of Dickey-Wicker Amendment but exercised the executive power instead of legal power to allocate funding

Immediately after President Bush took office in January 2001, he ordered “another look at the options regarding HESC research policy,” including a review of Rabb’s decision.²²⁷ Next, President Bush articulated his own policy by suspending the NIH’s implementation of funding and repealing the NIH Guideline.²²⁸ Some scientists and patients expressed anger and frustration with this decision.²²⁹

which human pluripotent stem cells were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; E. Research utilizing human pluripotent stem cells derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; F. Research in which human pluripotent stem cells are combined with an animal embryo; and G. Research in which human pluripotent stem cells are used in combination with somatic cell nuclear transfer for the purposes of the reproductive cloning of a human.

224. *Id.*

225. Nicholas Wade, *New Rules on Use of Human Embryos in Cell Research*, N.Y. TIMES, (Aug. 24, 2000) <http://www.nytimes.com/2000/08/24/us/new-rules-on-use-of-human-embryos-in-cell-research.html?pagewanted=all&src=pm>.

(President Clinton commented that the Guideline was a proper because “we cannot walk away from the potential to save lives and improve lives, to help people literally to get up and walk, to do all kinds of things we could never have imagined”).

226. Kyla Dunn, *The Politics of Stem Cells*, NOVA SCIENCE NOW, (Sept. 13, 2014, 3:37 PM), <http://www.pbs.org/wgbh/nova/body/stem-cells-politics.html>.

227. The President’s Council on Bioethics, *The Administration’s Human Embryonic Stem Cell Research Funding Policy: Moral and Political Foundations*, THE PRESIDENT’S COUNCIL ON BIOETHICS (Sept. 13, 2014, 4:11 PM), <https://bioethicsarchive.georgetown.edu/pcbe/index.html>.

228. *Id.*

229. Rick Weiss, *Bush Administration Order Halts Stem Cell Meeting; NIH Planned Session to Review Fund Requests*, WASH. POST, at A02 (Apr. 21, 2001) (reporting that one member of NIH criticized that “the decision certainly is holding up research that could potentially affect many of people with a number of different diseases Nobel laureate

On August 9, 2001, President Bush launched his newly crafted policy for HESC research in a national television speech. He announced that to avoid sanctioning or encouraging further destruction of human embryos, federal grants would only be available for research using the sixty four stem cell lines that were already in existence.²³⁰

President Bush's view on the ethics of HESC research were quite different from that of President Clinton.²³¹ Stem cell separation results in the deprivation of the embryo's human potential because it destroys the embryo. Thus, President Bush decided to "allow federal funds to be used for research on these existing stem cell lines, where the life-and-death decision has already been made."²³²

After the new policy was implemented, its moral, legal, and political implications were hotly debated among media, politicians, scientists, and organizations. The Bush policy was known as "The Bush Compromise." One reason for that characterization is that the policy apparently straddles the line between the conservative and liberal views on the question of governing federal funding. Another possible reason is that the policy tried to satisfy both the scientific communities and pro-life communities.²³³ To some extent, The Bush Compromise accepted the narrow view exemplified by the Dickey-Wicker Amendment. However, The Bush Compromise also adopted a new, broad concept of embryonic human life. In addition, The Bush Compromise changed the executive and legislative branches' positions on the question of federal funding for HESC research. It not only acknowledged Congress's sole authority to legislate but also exercised

Paul Berg feared that U.S. researchers stand to lose their edge in the biomedical revolution because Britain, France and Canada have been passing more liberal rules for research on embryo cells").

230. Press Release, White House, *White House Fact Sheet on Embryonic Stem Cell Research* (Aug. 9, 2001), available at <http://www.presidency.ucsb.edu/ws/?pid=79025..>

(The new policy provided as follows: "Federal funds will only be used for research on existing stem cell lines that were derived: (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors. No federal funds will be used for: (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose").

231. Press release, George W. Bush, *President George W. Bush's Address on Stem Cell Research* (Aug. 9, 2001), available at <http://edition.cnn.com/2001/ALLPOLITICS/08/09/bush.transcript/> (describing the embryo as "a snowflake in that each of these embryos is unique, with the unique genetic potential of an individual human being" and recommending that under the Bush policy, "a five-day-old cluster of stem cells is not an embryo, not yet an individual, but a pre-embryo").

232. *Id.*

233. Patrick Walsh, *Stemming the Tide of Stem Cell Research: The Bush Compromise*, 38 J. MARSHALL L. REV. 1061, 1077 (2005).

executive power to allocate funding.²³⁴ This new policy inevitably raised many concerns that scientists might move to other countries.²³⁵

5. The Report from the President Council on Bioethics clarified that the enforcement law was the Dickey Amendment

Following a public announcement on August 9th, President Bush established the Presidential Council on Bioethics. According to the Kass statement, the Council aims to provide “an adequate moral and ethical lens through which to view particular developments in their proper scope and depth.”²³⁶ It was quite different from previous councils because the White House was in charge of appointing its members. Chairman Kass proclaimed that the Council would listen to both religious and secular voices in its consideration of HESC research.

Following its proceedings, in January 2004, the Council published a report on monitoring stem-cell research. The report summarizes ethical, legal and policy issues around applications of stem cell research.²³⁷ The report concluded that the Dickey-Wicker Amendment was enforceable law. Federal funds should not be used to “encourage the exploitation or destruction of nascent human life, even if scientific and medical benefits might come from such acts.”²³⁸ The research should aim to cure deadly diseases provided it respects important moral boundaries. Meanwhile, the award of federal funding is a significant issue to be handled with care.²³⁹

234. O. Carter Snead, *The Pedagogical Significance of the Bush Stem Cell Policy: A Window into Bioethical Regulation in the United States*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 491, 498 (2005) (demonstrating “both an acknowledgement of Congress’s sole authority to appropriate federal funds and a robust exercise of the President’s authority as head of the executive branch to allocate the appropriated funding according to the [a]dministration’s priorities”).

235. See Tom Abate, *UCSF Stem Cell Expert Leaving U.S./Scientist Fears That Political Uncertainty Threatens His Research*, SAN FRANCISCO CHRONICLE, July 17, 2001, <http://www.sfgate.com/health/article/UCSF-stem-cell-expert-leaving-U-S-Scientist-2899802.php> (documenting one biology professor’s move from San Francisco to Britain in order to continue his research on human embryonic stem cells).

236. See *Monitoring Stem Cell Research: Reports by the President’s Council on Bioethics* (Jan. 2004), available at <https://bioethicsarchive.georgetown.edu/pcbe/>.

237. See Letter from Leon R. Kass M.D., Chairman of the President’s Council on Bioethics, to President Bush (March 31, 2004), available at <http://bioethics.georgetown.edu/pcbe/reports/reproductionandresponsibility/transmittal.html> (summarizing the main points addressed in the report).

238. Patrick Walsh, *Stemming the Tide of Stem Cell Research: The Bush Compromise*, 38 J. MARSHALL L. REV. 1061, 1077 (2005).

239. *Id.* at 1078 (proposing a four-part test to determine status of embryonic tissue for research and suggesting the President Bush institute a federal agency to oversee subsequent research).

The council also announced reports on alternative sources of stem cells, human cloning, human dignity, and bioethics. However, these reports did not have a substantial effect on public debate in the U.S.²⁴⁰ The Council's approach was criticized as "entertaining with the spectacle of enhanced bodies and immortal lives but offering little meaningful and substantive ethical analysis."²⁴¹

6. Executive order by President Obama: Reversing The Bush Compromise

Its practical import aside, The Bush Compromise had pedagogical significance for legal developments in regulating HESC research. The General Council of the President's Council on Bioethics evaluated The Bush Compromise as "provid[ing] an unparalleled window into the nature and substance of 'bioethical regulation' within the unique framework of the American system of government."²⁴² However, President Obama has expressed dissatisfaction with the policy restricting federal funding of HESC research.²⁴³

On March 9, 2009, President Obama signed an executive order to lift the ban on HESC funding. Research related to embryonic stem cell lines created after August 2001 could receive federal funding. Privately funded research was not affected. However, the creation of stem cell lines involving the destruction of embryos was still prohibited from receiving federal funds.²⁴⁴

The order did not clearly describe standards for which stem cell lines would be eligible for federal funds. The rule unlocking federal funding was challenged by the Dickey-Wicker Amendment, which prohibited

240. Leigh Turner, *Science, Politics and the President's Council on Bioethics*, 22 NATURE BIOTECH. 509, 509 (2004) (commenting that while the reports did not have "a dramatic effect on public debates," the recent membership shake up in the US President's Council put the Council "back in the limelight").

241. Leigh Turner, *Has the President's Council on Bioethics Missed the Boat?*, 327 THE BMJ 629, 629 (2003).

242. See Snead, *supra* note 235 at 234, at 492.

243. *Obama Overturns Bush Policy on Stem Cells*, CNN (Mar. 9, 2009), http://articles.cnn.com/2009-03-09/politics/obama.stem.cells_1_cancer-and-spinal-cord-embryonic-cell-research?_s=PM:POLITICS (quoting President Obama where he commented that "[i]n recent years, when it comes to stem cell research, rather than furthering discovery, our government has forced what I believe is a false choice between sound science and moral values"); see also Exec. Order No. 13,505, 3 C.F.R. 229 (2010).

244. See Exec. Order No. 13,505, 3 C.F.R. 229 (2010) (stating that Section 1 of the executive order provides as follows: "Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds").

funding of HESC research involving the destruction of embryos. The NIH attempted to finish answering a host of morally and politically complicated questions within 120 days.²⁴⁵ Because the order was challenged by the Dickey-Wicker Amendment, the President let Congress decide whether to overturn the statutory ban on federal funding on research related to embryo.²⁴⁶ Despite some weaknesses in the order, it is still a remarkable milestone in HESC research and as President Obama commented:

Today, with the Executive Order I am about to sign, we will bring the change that so many scientists and researchers; doctors and innovators; patients and loved ones have hoped for, and fought for, these past eight years: we will lift the ban on federal funding for promising embryonic stem cell research. We will vigorously support scientists who pursue this research. And we will aim for America to lead the world in the discoveries that it one day may yield.²⁴⁷

7. The result of the battle over the Dickey-Wicker Amendment: The Obama Administration funding policy of HESC research could move forward

NIH planned to implement new guidelines to suggest how federal funds should be used for HESC research.²⁴⁸ This was welcome news to scientists who had applauded President Obama's new policy.²⁴⁹ However, in a shocking case issued on August 23, 2010, a Federal District Court judge ruled against the Obama executive order.²⁵⁰ In *Sherley v. Sebelius*, the District Court held that federal funding for HESC research clearly violated the Dickey-Wicker Amendment, which prohibits research where a "human embryo is destroyed, discarded, or knowingly subject to risk of injury or

245. See Rob Stein, *Obama's Order on Stem Cells Leaves Key Questions to NIH*, THE WASHINGTON POST (Mar. 10, 2009), <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/09/AR2009030903156.html>.

246. See Sheryl Gay Stolberg, *Obama is Leaving Some Stem Cell Issues to Congress*, N.Y. TIMES (Mar. 8 2009), <http://www.nytimes.com/2009/03/09/us/politics/09stem.html>.

247. See Jesse Lee, "A Debt of Gratitude to So Many Tireless Advocates," WHITE HOUSE BLOG (Mar. 9, 2009, 12:09 PM), <http://www.whitehouse.gov/blog/09/03/09/A-debt-of-gratitude-to-so-many-tireless-advocates/>.

248. See generally Devin Dwyer, *NIH Issues New Stem Cell Research Guidelines as Obama Administration Prepares to Appeal Court Ruling*, POLITICAL PUNCH BLOG (Aug. 31, 2010) <http://abcnews.go.com/blogs/politics/2010/08/nih-issues-new-stem-cell-research-guidelines-as-obama-administration-prepares-to-appeal-court-ruling/>.

249. *Id.*

250. See *Sherley v. Sebelius*, 704 F. Supp. 2d 63, 71-72 (D.D.C. 2010) (overruling the National Institutes of Health Guidelines for Human Cell Research, which were promulgated in response to President Obama's Executive Order, because embryonic stem cell research involves the destruction of an embryo in violation of the Dickey-Wicker Amendment).

death greater than that allowed under applicable regulations.”²⁵¹

On the same day of the ruling, the Obama administration decided to appeal because of the judgment’s potential to block federal funding of HESC research.²⁵² On September 9, 2010, the United States Court of Appeals for the District of Columbia overturned the District Court’s ruling and provided temporary permission for federal funding of HESC research.

²⁵³ The harm caused by the District Court’s ruling “poured sand into that engine of discovery.”²⁵⁴ A few months later, at the request of the federal government, a federal appellate court reinstated the presidential policy and suspended the injunction issued by the district court.²⁵⁵

The court dispute over the Dickey-Wicker Amendment flared up again on April 29, 2011 when the appellate court permanently overturned the district court’s injunction, holding that the Dickey-Wicker Amendment was ambiguous.²⁵⁶ The NIH applauded the ruling, with a spokesperson stating, “I am delighted and relieved to learn of the decision of the Court of Appeals.”²⁵⁷ The ruling was reconfirmed on July 27, 2011, when a federal judge dismissed the legal challenge to government funding of HESC research.²⁵⁸ Ultimately, President Obama’s policy allowing funding for

251. *Id.* (finding that the new NIH Guidelines allowed federal funding of HESC research, which involves the destruction of embryos).

252. *See generally* Dwyer, *supra* note 248, 248 (criticizing that the ruling as one that could “cause irreparable damage and delay potential breakthroughs to improve care for people living with serious diseases and conditions . . . the injunction threatens to stop progress in one of the most encouraging areas of biomedical research”).

253. *See* Janice Hopkins Tanne, *US Court Temporarily Lifts Ban Imposed in August on Stem Cell Research*, THE BMJ (Sept. 10, 2010), <http://www.bmj.com/content/341/bmj.c4981>.

254. *Id.* (stating that “[t]he ruling threw the field into disarray, immediately halting some projects and causing the US National Institutes of Health (NIH) to put a hold on many research grants”).

255. *See* Ubaka Ogbogu, *US Appeal Court Reinstates Obama’s Funding Policy on Stem Cell Research*, STEM CELL NETWORK, (May 2, 2011), <http://scnblog.typepad.com/scnblog/2011/05/us-appeal-court-obama-funding-policy-stem-cell-research.html>.

256. *See* Bill Mears, *Appeals Court Lifts Ban on Federal Funding For Stem-Cell Research*, CNN, http://articles.cnn.com/2011-04-29/us/stem.cells_1_stem-cell-research-cell-types-ban-research?_s=PM:US (last visited July 14, 2014, 10:47 AM),.

257. Maggie Fox, *Appeals Court Hands Obama a Stem-Cell Victory*, NATIONAL JOURNAL (Apr. 29, 2011), <http://www.nationaljournal.com/healthcare/appeals-court-hands-obama-a-stem-cell-victory-20110429>.

258. George Annas, *Embryo research was born political*, STEM CELLS: BIOLOGY, BIOETHICS, AND APPLICATIONS (Oct. 28, 2010), <http://stemcellbioethics.wikischolars.columbia.edu/Legal+and+Political+History+of+Stem+Cell+Science> (reporting that the US Court of Appeals for the District of Columbia lifted an injunction imposed last year by a U.S. District judge, who said all embryonic stem cell

HESC research was allowed to proceed.

From the above, it is evident that law and morality often overlap, especially when the government is involved. Law shapes and provides a mechanism to balance various government interests including, curing diseases, scientific advances, and human dignity. The regulation of HESC research is not a simple permission or prohibition. In previous years, the complexity of this issue has been demonstrated by the federal government's strategies. Nevertheless, HESC research is worthy of attention from the White House and Congress. It appears as if the U.S. government takes the approach of patenting first and asking questions later. This hands-off approach is market oriented.²⁵⁹ Opponents have strongly criticized this approach for its lack of ethical and social considerations.²⁶⁰ Scientific research can be conducted with little public oversight. In addition, when federal funding is limited, private funding is still allowed, which might lead to even less moral considerations related to HESC research. Therefore, this article argues, it would be reasonable to remove moral review of HESC from the patent law. Regulating federal funding to HESC research is not only morally acceptable but also provides an important tool for monitoring HESC research. Federal funding should be allowed in HESC research; rather than patent law restrictions.

CONCLUSION

As has been demonstrated, few can deny the intrinsic link between HESC and morality.²⁶¹ This article argues that we should effectively control and monitor this questionable technology. The problem is whether such control should be within the patent law system. The approach adopted by the EU and China involves inserting moral provisions into their patent law to limit the patentability of inventions related to HESC, whereas the U.S. has not. The U.S. government's approach uses federal-funding control instead of patent control. Reviewing these various approaches,

research at the National Institutes of Health amounted to destruction of embryos, in violation of congressional spending laws).

259. See NATIONAL BIOETHICS ADVISORY COMMISSION, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 59 (1999), available at <https://scholarworks.iupui.edu/handle/1805/23> (discussing the causal link between federal support for basic biotechnology research and firms developing marketable products).

260. Michael J. Malinowsk and Nick Littlefield, *Transformation of a Research Platform Into Commercial Products: The Impact of United States Federal Policy on Biotechnology*, in TIMOTHY A. CAULFIELD AND BRYN WILLIAMS-JONES, *THE COMMERCIALIZATION OF GENETIC RESEARCH: ETHICAL, LEGAL AND POLICY ISSUES*, at 29-53 (1999).

261. See Warren-Jones, *supra* note 52, at 638-61.

morality should play the role of initially filtering what research is appropriate instead of regulating through the patent system.²⁶² Because even if the results of HESC research can be patented, HESC research could still be performed and funded. Therefore, immoral research should be prohibited at the beginning instead of at the patent-application stage. In addition, although the EU and China consider morality in granting patents, there is no direct moral standard, moral definition or defined meaning of industrial or commercial use, which inevitably results in legal inconsistency. It seems better to establish the specific authority to monitor HESC-related research pursuant to specific regulations before such research is conducted. Moreover, morality clauses in patent law aim to reduce the adverse impact of broad patents that might develop insupportable drugs and therapies. In terms of funds invested into such research, the reward represented by patent seems overvalued. Therefore, this article concludes, a patent system without a morality clause would be a critical step forward for HESC research. Infusing moral exclusions into patent law is both inefficient and ineffective.

262. *Id.* (concluding that “it is time that the core morality provision is no longer viewed as a fundamental regulator of new technology—it is an initial filter and it should never become more than that”).